Drake Willock™ System 1000
Dialysate Delivery System

510(k) Notification

APPENDIX A
APPLICATION OF CONNELL ET AL
FILED APRIL 19, 1991

Althin CD Medical, Inc.

Portland, Oregon

January 16, 1991

Food and Drug Administration
Bureau of Medical Devices & Diagnostic Products
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Gentlemen:

Attached is a Premarket Notification [510(k)] concerning the marketing of the Drake Willock^{TM} System 1000 dialysate delivery system.

If you have any questions, please feel free to contact Tom Kell y at (800) 547-5534 or (503) 659-3355.

Sincerely,

Gordon W. Robertson

Gordon W. Robertson
Director of Quality Assurance,
Regulatory and Medical Affairs

cc: T. Kelley
    A. Lewis
    M. Meyers

TMTrademark Althin CD Medical, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

RECEIVED JAN 3 1 1991

JANUARY 18, 1991

CD MEDICAL, INC.
ATTN: GORDON V. ROBERTSON
14600 N.W. 60TH AVENUE
MIAMI LAKES, FL 33014

510(k) Number: K910215
Received: 01-17-91
Product: DRAKE WILLOCK
SYSTEM 1000
DIALYSATE DELIVERY S

We have received the Premarket Notification you submitted in accordance
with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for
the above referenced product. We have assigned your submission a unique
510(k) number that is cited above. Please refer prominently to this 510(k)
number in any future correspondence that relates to this submission. We
will notify you when the processing of your premarket notification has been
completed or if any additional information is required.

The Safe Medical Devices Act of 1990, signed on November 28, states that
you may not place this device into commercial distribution until you
receive a letter from FDA allowing you to do so. As in the past, we intend
to complete our review as quickly as possible. Generally we do so within
90 days. However, the complexity of a submission or a requirement for
additional information may occasionally cause the review to extend beyond
90 days. Thus, if you have not received a written decision or been
contacted within 90 days of our receipt date you may want to check with FDA
to determine the status of your submission.

This legislation also requires anyone who asserts that a device is
substantially equivalent to a class III device to: (1) certify that they
have conducted a reasonable search of all information known, or otherwise
available, about the generic type of device; and (2) provide a summary
description of the types of safety and effectiveness problems associated
with the type of device and a citation to the literature, or other sources
of information, upon which they have based the description. The
description should be sufficiently comprehensive to demonstrate that an
applicant is fully aware of the types of problems to which the device is
susceptible. If you have not provided this certification and description
(with citations) in your premarket notification, please provide it as soon
as possible. We cannot complete the review of your submission until you do
so.

Please note that the Safe Medical Devices Act of 1990 may have additional
requirements affecting your device. You will be informed of these
requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Drake Willock™ System 1000 Dialysate Delivery System

510(k) Notification

Althin CD Medical, Inc.

Portland, Oregon

1

Summary

Althin CD Medical, Inc. (formerly CD Medical, Inc.) has developed a single patient delivery system that enhances some of the specifications of the currently commercially available Drake Willock™ 480 High Flow Single Patient Delivery System. The specification enhancements include automatic testing of essential monitors and alarm functions prior to dialysis, increased capability in dialysate and blood flow rates, and additional approved concentrate types and fluid pathway disinfects. These enhancements are consistent with the Fresenius A-2008E and the Cobe Centry 3 also currently commercially available.

Althin CD Medical, Inc. views certain parts of this notification as being **confidential** and, therefore, should not be divulged to the public. These parts are marked accordingly.

Althin CD Medical, Inc. feels that this enhanced delivery system matches existing patient care in hemodialysis. The company requests through this 510(k) Notification that the Commissioner determines the Drake Willock System 1000 Dialysate Delivery System to be substantially equivalent to other dialysis delivery systems currently commercially available.

™ Trademark of Althin CD Medical, Inc.

1. **Product Name:**

   Classification Name:
   Hemodialysis Delivery System

   Common Name:
   Single Patient Dialysate Delivery System

   Trade Name:
   Drake Willock System 1000 Dialysate Delivery System

   Project Name:
   Prior to the adoption of the trade name the delivery system was named SATRN.

2. **Registration Number:**

   Althin CD Medical, Inc., Portland, Oregon - 3019627
   Althin CD Medical, Inc., Miami Lakes, Florida - 1042431

3. **Product Class:**

   The June 20, 1977 Gastroenterology - Urology Panel Classification Device List indicates that single patient Dialysate Delivery Systems were recommended for Classification in Class II - Performance Standards.

4. **Action Taken to Comply with Section 514 - Performance Standards:**

   At this time, no Performance Standard for single patient Dialysate Delivery Systems has been adopted by the FDA. The product meets the provisions of the General Controls.

5. **Labeling:**

   a. Preliminary component identification labels are shown in Exhibit 1.

   b. Preliminary draft of the operator's manual is shown in Exhibit 2.

   c. Preliminary draft of the maintenance manual is shown in Exhibit 4.

6. **Product Description and Statement of Equivalence:**

   a. Description of Dialysate Delivery System

      The Drake Willock System 1000 Single Patient Dialysate Delivery System is a dialysate proportioning system for hemodialysis. The system fulfills the following functions:
      1)   mixes concentrate with water in the appropriate proportions to produce dialysate,
      2)   delivers dialysate at the appropriate temperature and ionic concentration to the dialyzer,
      3)   removes the appropriate amount of liquid from the patient's blood, and
      4)   along with the dialyzer and blood pump acts as a total artificial kidney.

   b. Description of Drake Willock System 1000 Dialysate Delivery System:

      The following information describes the methods and components utilized by the System 1000 Dialysate Delivery System to accomplish these functions:

1) Dialysate preparation:

The System 1000 Dialysate Delivery System volumetrically controls the proportion of water and concentrate(s) that are mixed to form dialysate.

"A" concentrate pump
> The "A" concentrate pump delivers a fixed volume of acid or acetate concentrate per pump stroke to the supply manifold. The ratio of acid concentrate to water to bicarbonate concentrate or acetate concentrate to water is controlled by the varying the relative number of pump strokes per minute.

Supply manifold
> The supply manifold has four main functions; e.g., control of incoming water flow, mixing of water and "A" concentrate, air removal, and measurement of the "A" concentrate – water conductivity.

"B" concentrate pump .
> For bicarbonate dialysis, the "B" concentrate pump delivers a fixed volume of bicarbonate concentrate per pump stroke to the "B" mix point.

"B" mix chamber
> Mixes the dialysate solution before it is monitored by the "B" conductivity probe.

"B" conductivity probe
> Measures the conductivity of the dialysate downstream of the "B" mixpoint.

2) Delivering dialysate to the dialyzer:

The System 1000 Dialysate Delivery System heats dialysate to the appropriate temperature and delivers it to the dialyzer.

Heat exchanger
> Transfers heat from the used dialysate to the incoming water for energy efficiency.

Water heater
> Warms the incoming water to the appropriate temperature for dialysis.

Temperature control thermistor
> Senses the water temperature as part of the heater control circuit.

Air removal sprayer and pump
> Cause dissolved air in the water to form into air bubbles later vented at the air trap.

Air trap
> Traps air bubbles formed in the dialysate and vents them to atmosphere.

Dialysate conductivity and temperature probe
> Senses the conductivity and temperature of the dialysate before it enters the dialyzer.

Temperature window
> Displays the temperature of the dialysate.

Conductivity window
> Displays the conductivity of the dialysate.

3) Removing liquid from the patient's blood (ultrafiltration):

The System 1000 Dialysate Delivery System volumetrically controls the removal of liquid from the patient's blood. By controlling exactly how much dialysate is going to and returning from the dialyzer, accurate fluid removal is achieved.

Flow equalizer
> Balances (matches) the flow of dialysate to and from the dialyzer.

Pressure equalizers
> Balance the pressures in the flow equalizer so that the flow equalizer chambers fill and empty at the same rate.

4

Dialysate pressure pump

    Controls the pressure in the dialysate compartment of the dialyzer, which affects the rate at which liquid is drawn from the blood compartment.

UF removal regulator

    Regulates the pressure in the UF flow meter circuit causing the positive pressure used to fill the flow meter chambers.

UF flow meter

    Removes a precise volume of spent dialysate from the post dialyzer circuit which inturn causes a like amount of liquid to be removed from the dialyzer blood compartment.

4) Along with the dialyzer and blood pump, acts as a total artificial kidney.

The System 1000 Dialysate Delivery System controls the flow of the extracorporeal blood to the dialyzer then back to the patient.

Blood pump

    Controls the extracorporeal blood flow.

Dialyzer

    Interfaces the blood and dialysate, allowing dialysis and ultrafiltration to take place.

c. Specifications of the System 1000 Delivery System

Physical Characteristics
    Cabinet dimensions:
        Height .... 60 in
        Width .... 17 in
        Depth .... 16 in
    Base dimension:
        Width .... 17 in
        Depth .... 27 in
    I.V. pole height .... 60 to 78 in
    Power cord length .... 10 ft
    Water line and drain line length .... 10 ft

Performance Characteristics
    Dialysate Circuit:
        Dialysate flow rate:
            Range.. 500 to 1000 ml/min
            (adjustable in 100 ml/min increments)
           Accuracy ....±3% of range
    Dialysate temperature:
        Range ....35 to 39°C
        Display:
            Range ....20 to 42°C
            Accuracy ....±0.3°C of range
        Alarm limits (fixed):
            Primary low .... 35 ±0.5°C
            Primary high .... 40 ±0.5°C
            Redundant high .... 41 ±0.5°C
    Dialysate conductivity:
        Display:
            Range...7 to 17 mS/cm
            Accuracy ....±0.2 mS/cm

Alarm limits:

    Primary ....±5% of the indicated conductivity
                              when the conductivity was verified during Self Test
    Backup low (fixed)...12 mS/cm
    Backup high (fixed) ....16 mS/cm
    Redundant...............................±10% of desired A and B probe conductivites

Dialysate proportioning:
    Ratio:
        Default value:
            Acetate ....34 parts water to 1 part acetate cencentrate
            Bicarbonate ....34 parts water to 1 part acid cencentrate to 1.8 parts
                                  bicarbonate concentrate
        Optional values (technician settable):
            "F" type bicarbonate ....32.77 parts water to 1 part acid
                         concentrate to 1.23 parts bicarbonate concentrate
            "C" type bicarbonate.................................42.6 parts water to 1 part acid
                          concentrate to 1.4 parts bicarbonate concentrate
    Accuracy ....±2%

Patient Monitoring:
    Venous pressure display:
        Range.. −400 to +600 mmHg
        Accuracy ....±20 mmHg or 10% of reading
                                  (whichever is greater)
        Alarm limits...Automatically set
        Minimum low alarm limit (dialyze mode) ....+10 mmHg
    Arterial pressure display:
        Range.. −400 to +600 mmHg
        Accuracy ....±20 mmHg or 10% of reading
                                  (whichever is greater)
        Alarm limits...Automatically set
    Transmembrane pressure display:
        Range.. −100 to +600 mmHg
        Accuracy ....±20 mmHg or 10% of reading
                                  (whichever is greater)
        Alarm limits...Automatically set
    Blood leak detector sensitivity (fixed)..35 mg Hb/L
                          (at 500 mL/min dialysate flow rate)
    Air detector sensitivity:
        Primary ....air bubbles exceeding 10 µl in venous blood line
        Redundant.......................air bubbles exceeding 300 µl in venous blood line

Volumetric Ultrafiltration Control:
    Rate range ....0.1 to 4 L/h
    UF accuracy:
        System ....±50 ml/h
        Display ....±1% full scale

Blood pump:
    Flow rate range ....100 to 700 ml/min
    Speed accuracy...±10% of indicated reading
                               (excluding tubing variations)
    Pump segment selection:
        Inside diameter... 1/4-in, 6-mm, 7-mm or 8-mm
        Wall thickness ....0.8 to 1.65 mm (0.03 to 0.065 in)

.

Heparin pump:

Infusion rate range ....0.5 to 5.5 ml/h

Accuracy ....±5%

(excluding syringe variations)

Syringe:

Size ....10 or 20 ml (cc)

Type .... B-D Plastipak, Monojet, Terumo or equivalent

(Calibrated to specific syringe type.)

Electrical Characteristics:

The System 1000 Single Patient Delivery System is available in 110, 120, 220, and 240 V 50 or 60 Hz configurations. Each nominal voltage has a tolerance of ±10%. The electrical requirements described below illustrate the most common configuration:

Voltage, nominal .... 120 V

Frequency .... 60 Hz

Current required .... 15 A

Current leakage (maximum):

Dialysate to ground .... 100 µA

Chassis to ground .... 100 µA

Environmental Characteristics

Water requirements:

The incoming water must be of adequate quality or treated to comply with the attending physician's directives. The water supply between the water treatment unit and the dialysis machine must be made of materials that do not contaminate the treated water supply and that allow for chemical disinfection of the plumbing. It is recommended that water meet the AAMI standard for water used in hemodialysis and have zero detectable iron.

Pressure (at the flow rate of 1000 ml/min):

Minimum ....10 psig (0.7 bar)

Maximum ....100 psig (7 bar)

Temperature:

Minimum ....6°C

Maximum ....32°C

Flow rate (minimum):

Standard flows (500 to 600 ml/min)... 600 ml/min

Rapid dialysis (>600 ml/min) .... 1000 ml/min

Drain requirements:

Vented; Adequate air gap

Flow capacity, minimum ....1.5 L/min

Drain height, maximum above floor ....56 cm (22 in)

Power dissipation to environment:

Approximately .... 250 W

Operating environment:

Temperature ....18 to 40°C (64 to 104°F)

Humidity, relative (non-condensing) ....10 to 95%

All listed specifications are nominal.

d. Copy of the laboratory report is shown in Exhibit 3.

e. Product equivalence

The Drake Willock System 1000 Dialysate Delivery System is substantially equivalent to the following other products which are currently in commercial distribution:

7

1) Drake Willock 480 High Flow Dialysate Delivery System - Althin CD Medical, Inc., Portland, Oregon.

2) Fresenius A-2008 D - distributed by Fresenius USA, Concord, California

3) Cobe Centry 3 - Cobe Laboratories, Inc., Lakewood, Colorado.

Features comparison matrices of the different systems is shown is Tables 1 and 2. From this comparison, equivalent system functionality is clearly demonstrated.

Table 1

	Drake Willock System 1000	Drake Willock 480 High Flow	Fresenius 2008E	Cobe Centry 3	Braun Secura
UF C ntr l					
Volumetric	0.1 to 4 L/h	0.0 to 2.4 L/h	0.0 to 2 L/h	0.0 to 2.4 L/h	0.05 to 2.0 L/h
	Yes	Yes	Yes	Yes	Volumetric Measurment/ TMP Control
Programmable	Yes	No	Yes	Yes	Yes
UF Removed Display	Yes	Bag Level	Yes	Yes	Yes
Proportioning	Volumetric	Volumetric	Volumetric	Servo	Servo
Sodium Range	130 to 160 mEq/L	130 to 150 mEq/L	130 to 155 mEq/L	130 to 160 mEq/L	?
Bicarbonate	28 to 42 mEq/L	Fixed	±8 mEq/L	25 to 40 mEq/L	Bicarb is an option
Programmable Na	Yes	No	Yes	Yes	Yes
Programmable Bic	Yes	No	Yes	Yes	No
Dialysate Flow Rate	500 to 1000 mL/min	500/750 mL/min	500 to 800 mL/min	250 to 600 mL/min	500 mL/min (300 to 600 mL/min internal adjustment)
Blood Flow Rate	100 to 700 mL/min	To 650 mL/min	To 600 mL/min With 8 mm segment	50 to 500 mL/min	0 to 400 mL/min
Heparin Pump	0.5 to 5.5 mL/h	0.5 to 5.5 mL/h	0.6 to 10 mL/h	0.5 to 5.5 mL/h	0.5 to 5.5 mL/h
Syringe size	10 to 20 mL	20 to 30 mL	10 to 20 mL or 30 to 50 mL	10 to 20 mL	Peristaltic Pump
Level Adjust	Powered Art., Ven.	Yes	Powered (Venous only)	None	None
KUF Limit	No	No	No	No	40 mL/h/mmHg
Disinfection	Heat/Chemical	Chemical	Heat/Chemical	Chemical	Heat/Chemical
Pressure Reading					
Arterial	+600 to –400 mmHg	+400 to –300 mmHg	+300 to –300 mmHg	+400 to –200 mmHg	+400 to –250 mmHg
Venous	+600 to –400 mmHg	+400 t –300 mmHg	+500 to –100 mmHg	+400 to –200 mmHg	+350 to 20 mmHg
TMP	Yes	No	Yes	Yes	Yes

9

Table 2
continued

Syst m 1000 Dialysis D liv ry Syst m

Proportioning Rati :
Default value:
Acetate ....34 parts water to 1 part acetate
cencentrate
Bicarbonate . 34 parts water to 1 part acid cencentrat to
1.8 parts bicarbonate concentrate
Optional values (technician settable):
"F" type bicarbonate ....32.77 parts water to 1 part
acid concentrate to 1.23 parts
bicarbonate concentrate
"C" type bicarbonate ....42.6 parts water to 1 part acid
concentrate to 1.4 parts
bicarbonate concentrate

Accuracy..±2%

C nductivity:

Monitor range ....7 to 17 mS/cm

Accuracy...±0.2 mS/cm

Alarm limits

Primary ....± 5%

Note: The alarm limits set automatically before dialysis begins
eliminating the risk that the operator could inadvertently fail
to set the alarm limits.

Backup high (fixed)............................16 mS/cm

Backup low (fixed) ....12 mS/cm

Redundant.........± 10 % of the desired "A" and "B" probe
conductivities

Note: Redundant conductivity alarm uses a separate conductivity
probe and alarm circuitry.

Conductivity Alarm Response
· Dialysate bypassed
· Audio alarm sounds
· Main alarm lamp flashes
· Window around conductivity display flashes
· Elasped time of dialysis timer stops (provides a more
accurate indication of the treatment delivered to the
patient).
· Machine status window displays ALARM
· The alarm automatically is cleared when the conductivity
is at least 0.1 mS/cm into the permissible conductivity
window.

Programmable Sodium

Sodium Variability........................ 130 to 160 mEq/L

Programmable Bicarbonate

Bicarbonate Variablity .... 28 to 42 mEq/L

N Water Supply Alarm......................Creates an alarm when the
water supply is off for 30
seconds

Alarm Response
· Audio alarm
· Visual alarm

Bypass Fail Alarm ....Alarms if the bypass valve fails to divert
the flow of dialysate away from the dialyzer
during a conductivity or temperature alarm

Alarm Response
· Shuts down flow equaliz r stopping flow to the dialyzer
· Audio alarm
· Visual alarm
· Flashing rror message

480 High Flow Dialysis D liv ry System

Proportioning Ratio

Acetate .... 34 parts water to 1 part acetate
concentrate

Bicarbonate ....34 parts f water to 1 part acid concentrate
to 1.8 parts bicarbonate concentrate

Proportioning accuracy ....+2 to -4%

Note: The bicarbonate concentrate used must contain 59 mEq/L of
sodium.

Conductivity:

Meter range .... 12 to 16 mS/cm

Accuracy...±0.2 mS/cm

Alarm limits adjustability range:

Primary low .... 12 to 13.6 mS/cm

Primary high .... 13 to 16 mS/cm

Note: The primary limits must be set an operator prior to dialyzing
patient.

Backup high .... 15.7 mS/cm

Backup low .... 12.4 mS/cm

Conductivity Alarm Response
· Dialysate bypassed
· Audio alarm sounds
· Main alarm lamp flashes
· Conductivity alarm lamp flashes
· The alarm automatically is cleared when the
conductivity is at least 0.1 mS/cm into the permissible
conductivity window.

No Water Supply Alarm......................Creates an alarm when the
water supply is off

Alarm Response
· Audio alarm
· Visual alarm

Table 2
continued

System 1000 Dialysis Delivery System

Volumetric Ultrafiltration Control

Ultrafiltration rate range ....0.1 t 4 L/h
- Automatically calculated by setting Prescribed Time of Dialysis and Target Fluid Loss or Manually set with UF rate adjust
- Ultrafiltrate Removed display shows total fluid removed during the treatment
- UF System checked dynamically during the Self Test state, will not allow operator to dialyze patient if the system is inaccurate. This eliminates the risk that the operator will fail to check the UF system before the machine is used.

UF accuracy

System .... ±40 mL/h

UF removed monitor..±1% full scale

This variable is programmable.

Prescribed Time of dialysis display
Operator sets the Prescribed Time of dialysis. When machine enters Dialyze Mode display changes to Elasped Time of dialysis which records the actual treatment time.

Elasped Time of dialysis does not count time when the blood pump is off or when the dialysate bypasses the dialyzer ensuring that the prescribed dialysis time is reached and improving treatment quality assurance.

Patient Monitoring:

Venous pressure gauge range ....–400 to +600 mmHg

Accuracy ....±20 mmHg or 10% of reading
(whichever is greater)

Arterial pressure gauge range ....–400 to +600 mmHg

Accuracy ....±20 mmHg or 10% of reading
(whichever is greater)

- Pressure monitor accuracy and alarms are automatically tested in the self test mode.
- The arterial and venous alarm limits automatically set 10 seconds after the blood pump has started preventing the risk that a machine operator would forget to set the alarms.
- Minimum venous alarm limit (Dialyze mode) +10 mmHg

Transmembrane pressure range:

TMP Monitor .... 600 to –100 mmHg

Accuracy ....±20 mmHg or 10% of monitor reading
(whichever is greater)

Note: One minute after the treatment begins the alarm limits form a window ±35 mmHg from the desired TMP. The machine will not allow a limit to set which is greater than +500 mmHg or less than –80mmHg, so the machine will alarm to alert the operator if pressures are present in the hydraulics which could damage the dialyzer membrane.

Blood leak detector sensitivity (fixed):
(at 500 mL/min dialysate flow rate)

Nominal sensitivity....................................... 35 mg Hb/L

- Automatically tested in the Self Test mode

Air detector sensitivity ....air bubbles xceeding 10 µL
in th venous blood lin

480 High Fl w Dialysis Deliv ry Syst m

Volumetric Ultrafiltration Control:

Ultrafiltration rate rang ....0.1 to 2.5 L/h
- Manually set with UF flow control kn b
- Ultrafiltrate Collection Bag will collect a volumetric equivalent to the patients ultrafiltrate.
- Manual check of the UF balancing system is required before dialysis. The risk of the manual check is that occasionally operator's forget to perform the check.

UF accuracy

System .... ±60 mL/h

UFR flowmeter .... ±2% full scale

UF Collection Bag ....±2% full scale

Patient Monitoring:

Venous pressure gauge range.....................–300 to +400 mmHg

Accuracy ....±20 mmHg or 10% of reading
(whichever is greater)

Arterial pressure gauge range ....–300 to +400 mmHg

Accuracy ....±20 mmHg or 10% of reading
(whichever is greater)

- Arterial and venous alarm limits are manually set by the operator.

Dialysate pressure range ....–400 to +400 mmHg

Dialysate pressure meter range ....–440 to +400 mmHg

Accuracy ....±20 mmHg or 10% of meter reading
(whichever is greater)

Note: Dialysate pressure alarm limits manually set by operator.

Blood leak detector sensitivity (adjustable):
(at 500 mL/min dialysate flow rate)

Minimum sensitivity .... 70 mg Hb/L

Nominal sensitivity... 35 mg Hb/L

Air detector sensitivity ....air bubbles exceeding 10 µL
in the venous blood line

Table 2
continued

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System 1000 Dialysis D livery System

Redundant air detector sensitivity .... air bubbles exceeding 300 µL in the venous blood line
- Disarm limited to 5 minutes in the Prime mode. Air detector *cannot* be disarmed in the Dialyze mode, ensuring that the extracorporeal blood line will always be monitored for air bubbles whenever a patient is on the machine.
- Air detector function is verified in the Self Test mode.

Blood pump:

Flow rate range .... 100 to 700 mL/min

Speed accuracy .... ±10% of indicated reading, excluding tubing variations

Pump segment selection:

Inside diameter .... 1/4-in, 6-mm, 7-mm or 8-mm

Wall thickness............................ 0.8 to 1.65 mm (0.03 to 0.065 in)

- Pump stops when the cover is open.
- Blood pump shuts down in overspeed condition
- Blood pump underspeed alarm
- Blood pump stop alarm
- Built in handle to return blood in case of power failure.
- Elasped Time of Dialysis does not count time when the blood pump is off

Heparin pump:

Infusion rate range

(B-D Plastipak, Monoject, Terumo syringe or equivalent, calibrated to specific syringe type)

10 mL (cc) syringe .... 0.5 to 5.5 mL/h

20 mL (cc) syringe .... 0.5 to 5.5 mL/h

Accuracy (not including syringe variations)

Pump .... ±5%
- End of stroke alarm
- Overspeed alarm
- Overpressure alarm

Heparin Pump Alarm Response
- Audio alarm
- Visual alarm
- Heparin pump shuts off
- Operator alerted to specific heparin pump alarm condition

Drip chamber level adjustment
- Powered level adjust
- For arterial and venous drip chambers

Dialyzer connector interlock
- The machine knows if the dialysate lines are not on the dialyzer.
- Prevents the machine from going into rinse if the dialysate connectors are not connected to the rinse block.

Approved Disinfectants
- Household bleach (5.25% Sodium Hypochorite)
- 37% F rmaldehyde
- Actril
- Nephrex
- Heat

480 High Flow Dialysis Delivery Syst m

- Air detector can be disarmed in any mode.

Blood pump:

Flow rate range .... 100 to 650 mL/min

Speed accuracy .... ±10% of indicated reading, excluding tubing variations

Pump segment selection:

Inside diameter .... 1/4-in, 6-mm, 7-mm r 8-mm

Wall thickness............................ 0.8 to 1.65 mm (0.03 to 0.065 in)

- Pump stops when the cover is open.
- Blood pump shuts down in overspeed condition
- Blood pump stop alarm
- Built in handle to return blood in case of power failure.

Heparin pump:

Infusion rate range

(B-D Plastipak™ syringe or equivalent)

30 mL (cc) syringe .... 0.5 to 5.5 mL/h

20 mL (cc) syringe .... 0.4 to 4.4 mL/h

Accuracy (B-D Plastipak syringe or equivalent)

Pump .... ±5%
- End of stroke alarm
- Overspeed alarm
- Overpressure alarm

Heparin Pump Alarm Response
- Audio alarm
- Visual alarm
- Heparin pump shuts off

Drip chamber level adjustment
- Manual level adjust
- For arterial and venous drip chambers

Approved Disinfectants
- Household bleach (5.25% Sodium Hypochorite)
- 37% Formaldehyde

Table 2
continued

Syst m 1000 Dialysis Delivery System

480 High Fl w Dialysis D livery Syst m

H ur m ter

Dialysis Treatment Data Report

Provides precise treatment data n the f llowing variables
enhancing treatment Quality Control.
- Prescribed time of dialysis
- Remaining time of dialysis
- Elasped time of dialysis (only records dialysis time with
  dialysate flow to the dialyzer and the blood pump on).
- Target UF
- UF removed
- Total blood processed
- Total heparin infused
- Current date and time
- If the operator set a manual or calculated UF rate

Self Test Mode - The self test mode tests the critical safety and
perating systems of the System 1000 machine prior to dialysis.
If the machine does not pass a successful self test the machine
will not be able to dialyze a patient. The following systems are
checked during a self test:
- Conductivity alarms
- Temperature alarms
- Air detector
- Blood leak detector
- UF system integrity
- Arterial and venous pressure monitoring and alarm system
- Audible alarm
- Main alarm lamp

Physical Characteristics

Cabinet dimensions:

Height	60 in
Width	17 in
Depth	16 in

Base dimension:

Width	17 in
Depth	27 in

IV pole height	60 to 78 in
Power cord length	10 ft
Water line and drain line length	10 ft

Required Environmental Conditions

Water requirements:

The incoming water must be treated to comply with the
attending physician's directives. The water supply system
between the water treatment unit and the delivery system
must be made of materials that do not contaminate the
treated water supply and that will allow for chemical
disinfection of the plumbing system. It is recommended that
treated water meet the AAMI Standard for water used in
hemodialysis and have zero detectable iron.

Water pressure (at the flow rate of 1000 mL/min)

Minimum	10 psig (0.7 bar)
Maximum	100 psig (7 bar)

Physical Characteristics

Cabinet dimensions:

Height	47 in
Width	21 in*
Depth	13 in

* IV pole adds 3 1/2 inches to width

Base dimension:

Width	19 in
Depth	27 in

IV pole height	48 to 71 in
Power cord length	10 ft
Water line and drain line length	10 ft

Required Environmental Conditions

Water requirements:

The incoming water must be treated to comply with the
attending physician's directives. The water supply system
between the water treatment unit and the delivery system
must be made of materials that do not contaminate the
treated water supply and that will allow for chemical
disinfection of the plumbing system. It is recommended that
treated water meet the AAMI Standard for water used in
hemodialysis and have zero detectable iron.

Water pressure (at the flow rate of 750 mL/min)

Minimum	20 psig (1.4 bar)
Maximum	100 psig (7 bar)

Table 2
continued

System 1000 Dialysis Delivery System

Incoming water temperature

    Minimum ....6°C

    Maximum ....32°C

Incoming water flow rate minimum

    Standard flows (500 to 600 mL/min)..............600 mL/min

    Rapid dialysis (>600 mL/min) ....1000 mL/min

Drain requirements:

    Vented; Adequate air gap

    Flow capacity, minimum ....1.5 L/min

    Drain height, maximum above floor ....56 cm (22 in)

Power dissipation to environment:

    Approximately .... 250 W

Operating environment:

    Temperature ....18 to 40°C (64 to 104°F)

    Humidity, relative (non-condensing)........................ 10 to 95%

Electrical power operation............................120 Vac ±10%, 60 Hz

    Current required .... 15 A

    System current leakage..<100 µA

Memory of essential treatment parameters in power failure

480 High Fl w Dialysis D livery System

Incoming water temperature

    Minimum .... 4°C

    Maximum ....32°C

Incoming water flow rate minimum........................ 750 mL/min

Drain requirements:

    Vented; Adequate air gap

    Flow capacity, minimum .... 2.8 L/min (0.26 gal/min)

    Drain height, maximum above floor ....46 cm (18 in)

Power dissipation to environment:

    Approximately .... 250 W

Operating environment:

    Temperature ....18 to 40°C (64 to 104°F)

    Humidity, relative (non-condensing)........................ 10 t 95%

Electrical power operation............................ 120 Vac ±10%, 60 Hz

    Current required ....12 A

    System current leakage...<100 µA

Rinse valve

Bypass valve

Dialysate monitoring manifold

Output pressure equalizer

Flow sensors

Blood leak detector

Dialyzer

Flow equalizer

Dialysate pressure pump

Input pressure equilizer

UF removal regulator

Flow restrictor

UF flow meter

"B" concentrate pump

"A" concentrate pump

Supply regulator

"B"

"A"

Supply valve

Dialysate filter

Air gap chamber

Air removal sprayer

Air trap

"B" conductivity probe

Supply pump

Supply manifold

"B" mix chamber

Air removal pump

"A" conductivity probe

Rinse ports

Water

Water pressure regulator

Thermistor

Heat exchanger

Water on/off valve

Heater

Drain

Drake Willock™ 480 High flow fluid path

Legend:
- Incoming water
- Acid/acetate concentrate
- Bicarbonate concentrate
- Acetate dialysate or acid/water mixed
- Bicarbonate Dialysate
- Effluent Dialysate
- Line number

Labels:
Incoming water pressure regulator
Test port
Drain
Heat exchanger
Effluent dialysate from blood leak detector
Thermistor
Safety thermostat
Heater
A/Ac rinse port pressure regulator
Acid/acetate concentrate cylinder
Bicarbonate concentrate cylinder
Shift cam
No supply pressure switch
Bicarbonate input
"B" mix point
Bicarbonate fixed-ratio volumetric proportioning pump
Air removal sprayer
Mix point pressure regulator
Inport
Outport
Check valve
Routing valve
Acid/acetate input
Pre pump pressure regulator
Air removal pump
Mix chamber
Air trap
"B" rinse port
To Ultrafiltration Control Module
Variable proportioning pump

18

.

Drake Willock™ 480 High flow fluid path, part 2 of 2

Fresenius Fluid Path

1. Filter
2. Pressure regulator
3. Valve
4. Heat exchanger
5. Heater
6. Temperature sensor
7. Float switch
8. Air removal chamber
9. Concentrate pump
10. Air removal pump
11. Conductivity sensor
12. Air separator
13. Blood leak detector
14. Pressure transducer
15. Balancing chamber
16. UF pump
17. Pump
18. Rinse port
19. Mix chamber
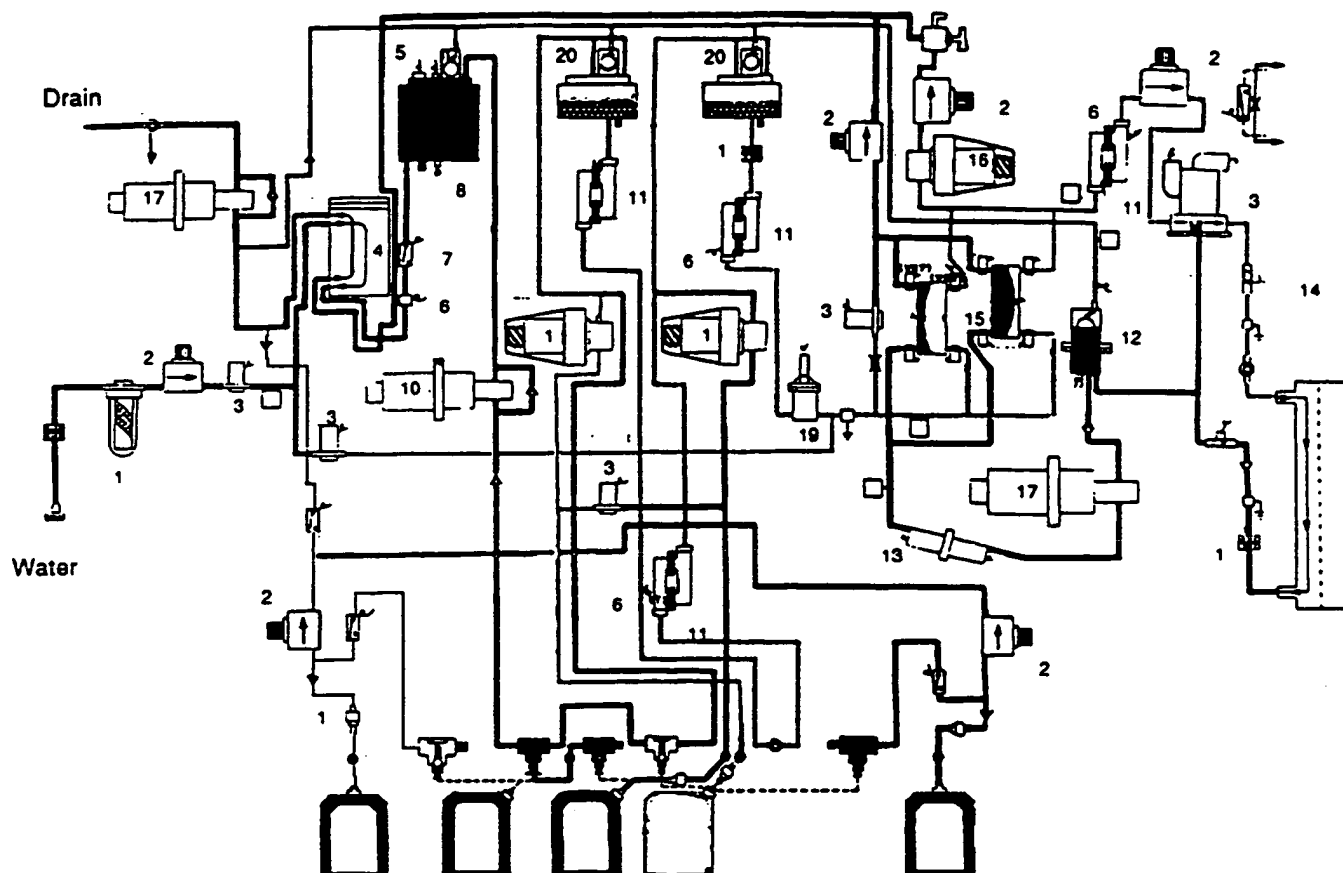
Cobe Centry 3 Fluid Path

1.	Filter	19.	pH sensor
2.	Pressure regulator	20.	Mix chamber
3.	Valve		
4.	Heat exchanger		
5.	Heater		
6.	Temperature sensor		
7.	Flow switch		
8.	Air removal chamber		
9.	Concentrate pump		
10.	Air removal pump		
11.	Conductivity sensor		
12.	Air separator		
13.	Blood leak detector		
14.	Pressure transducer		
15.	Balancing chamber		
16.	UF pump		
17.	Pump		
18.	Rinse port		

Panel 1 (top)

Arterial Pressure

Venous Pressure

mmHg

+600 +600
+500 +500
+400 +400
+300 +300
+200 +200
+100 +100
0 0
-100 -100
-200 -200
-300 -300
-400 -400

Heparin Pump
ml/h

Dialysate Flow
ml/m

Conductivity
mS/cm

Temperature
°C

Prescribed Time
h:m

Target UF
L

TMP
mmHg

UF Rate
L/h

100 200 300 400 500 600 700

Blood Pump   ml/m

RESET
HELP
SET LIMITS
MENUS
RINSE
MUTE
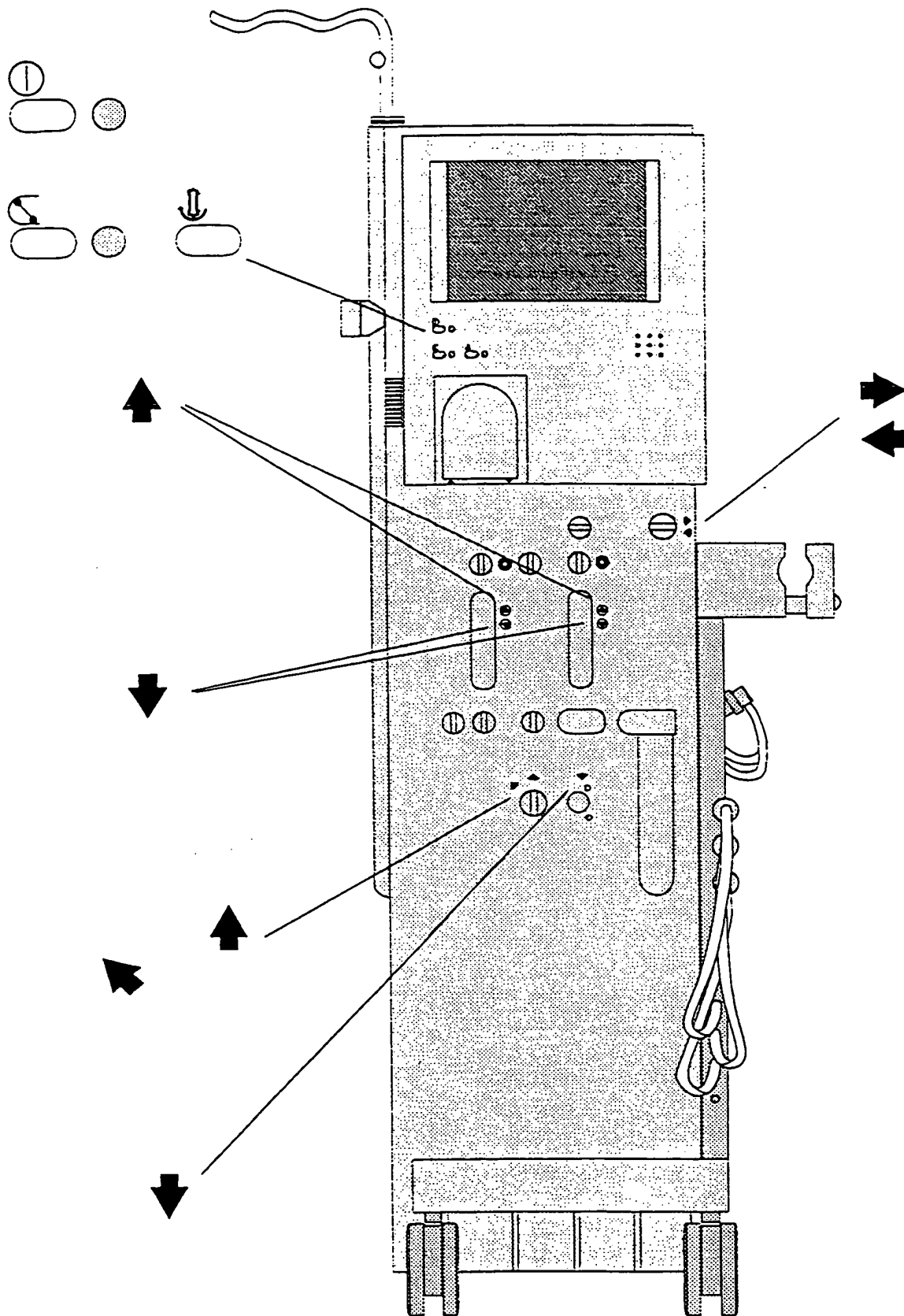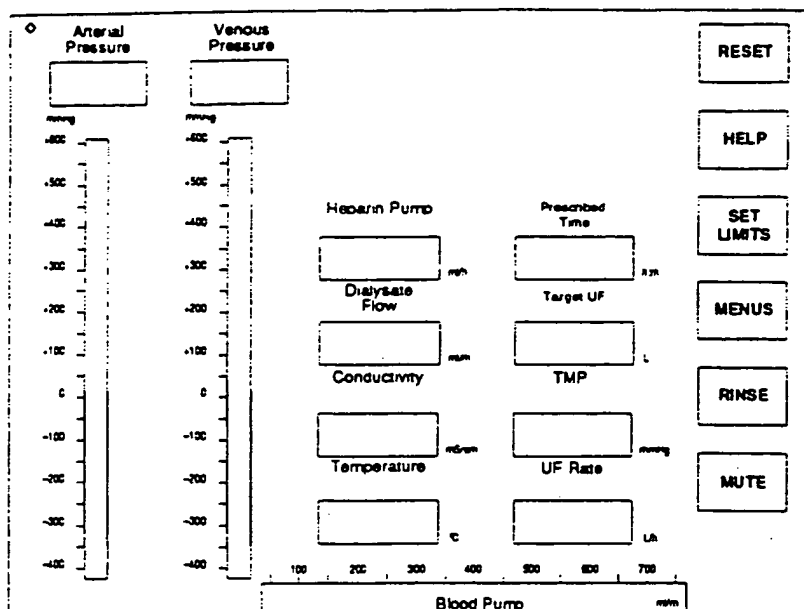
TEST   PRIME   MAIN SCREEN

ARMED/DISARM   PROGRAM

SND

START   DATA REPORT

Q_b VERIFY Q_d VERIFY   BOLUS

Panel 2 (bottom)

Arterial Pressure

Venous Pressure

mmHg

+600 +600
+500 +500
+400 +400
+300 +300
+200 +200
+100 +100
0 0
-100 -100
-200 -200
-300 -300
-400 -400

Heparin Pump
ml/h

Dialysate Flow
ml/m

Conductivity
mS/cm

Temperature
°C

Elapsed Time
h:m

UF Removed
L

TMP
mmHg

UF Rate
L/h

100 200 300 400 500 600 700

Blood Pump   ml/m

RESET
HELP
SET LIMITS
MENUS
RINSE
MUTE
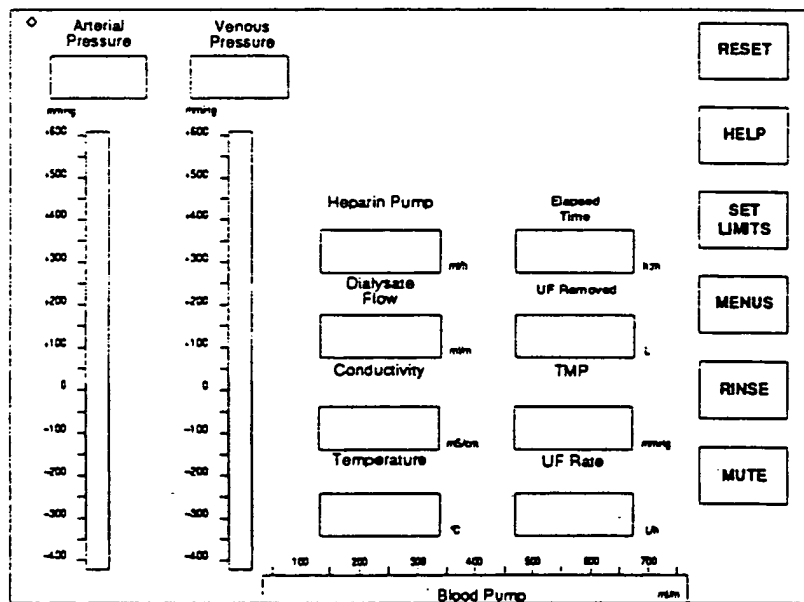
MAIN SCREEN

PROGRAM

SND

START   DATA REPORT

Q_b VERIFY Q_d VERIFY   BOLUS

RESET HELP ARMED/DISARMED MENUS RINSE MUTE

Prescribed Time 4:00 h:m
Target UF 6.00 L
TMP 55 mmHg
UF Rate 1.50 L/h

Heparin Pump Rate 5.0 mL/h
Dialysate Flow 500 mL/m
Conductivity 14.20 mS/cm
Temperature 38.0 °C

Arterial Pressure 00 mmHg
Venous Pressure 00 mmHg

PRIME

Blood Pump

+600 +500 +400 +300 +200 +100 0 −100 −200 −300 −400

100 200 300 400 500 600 700
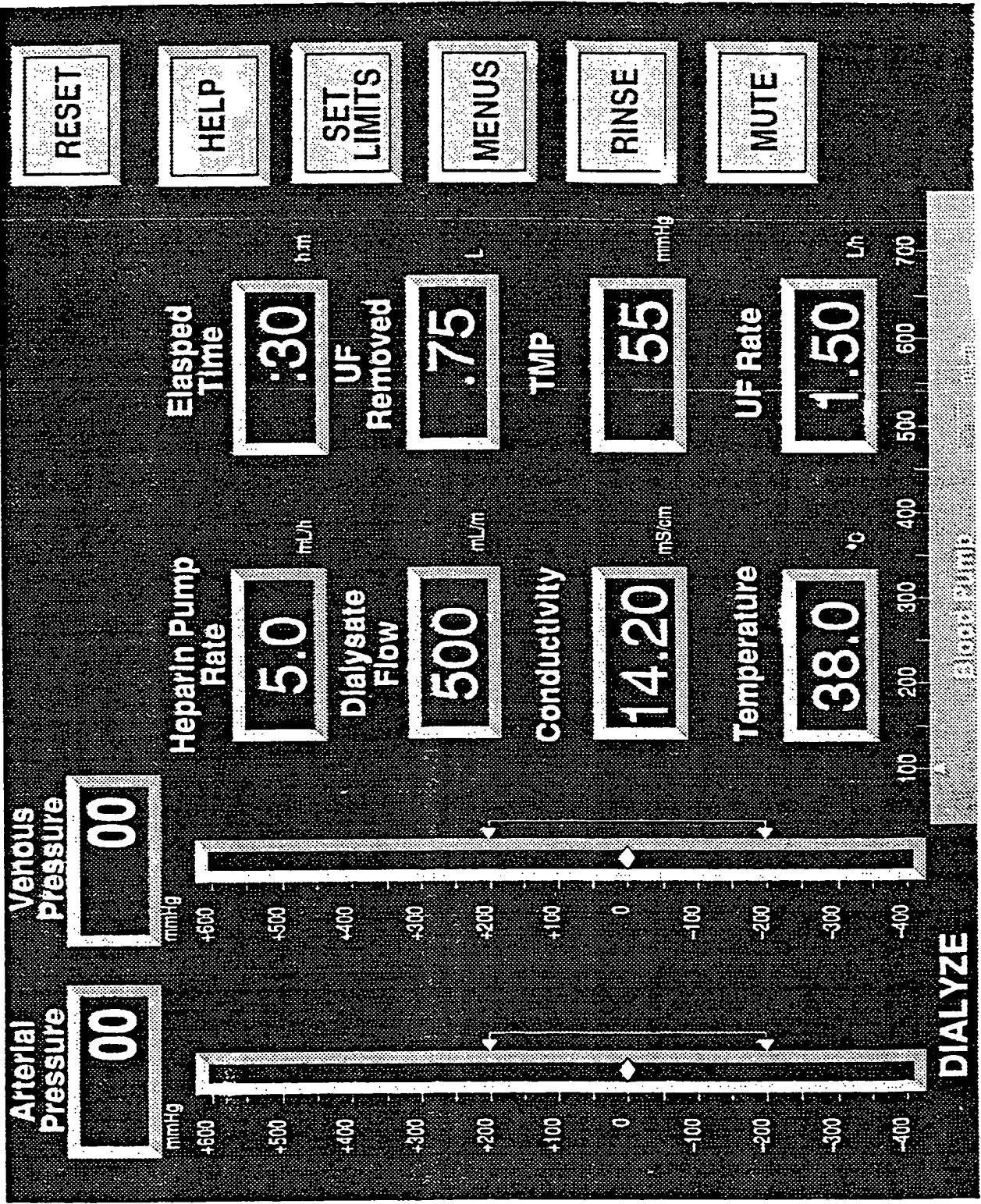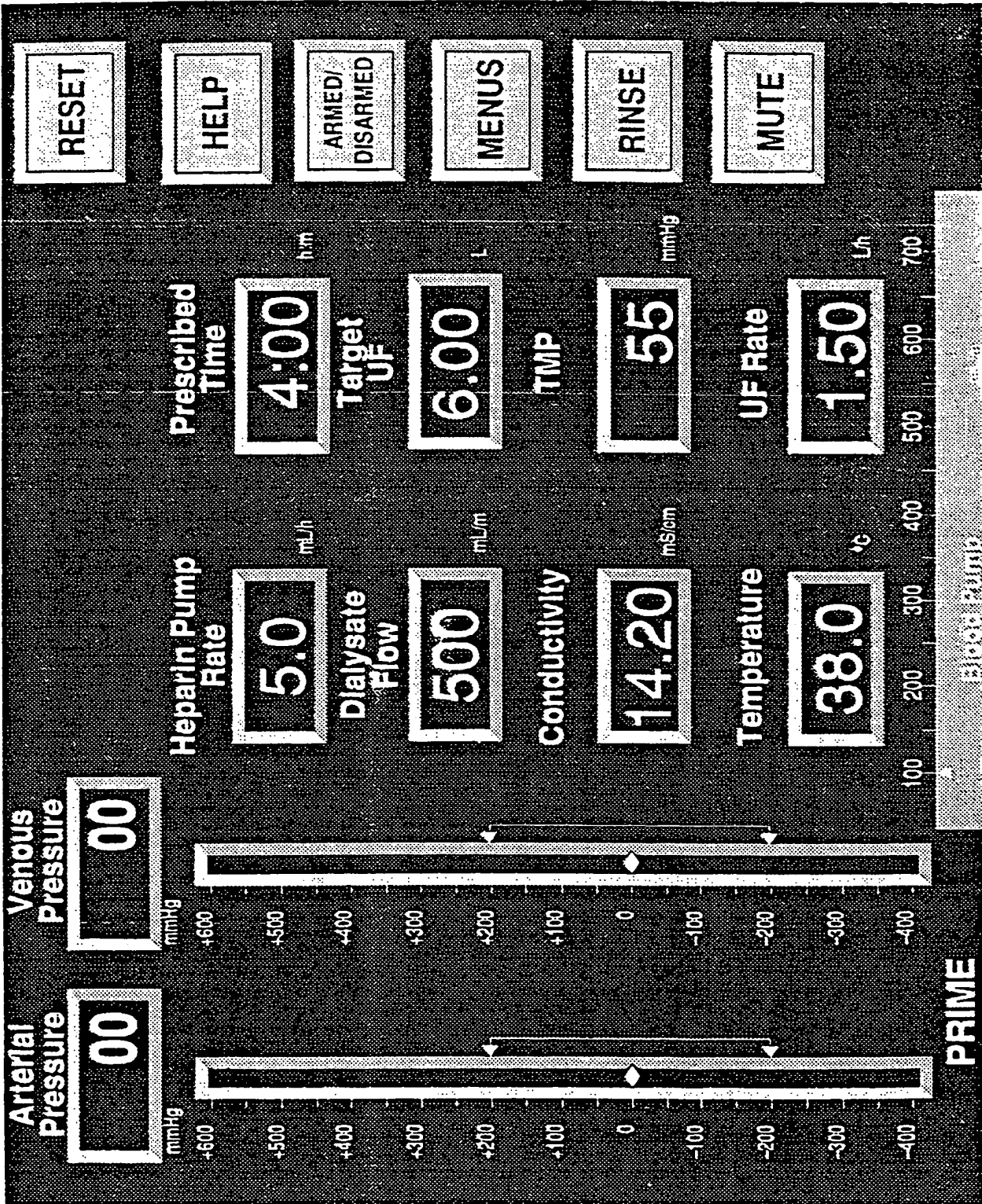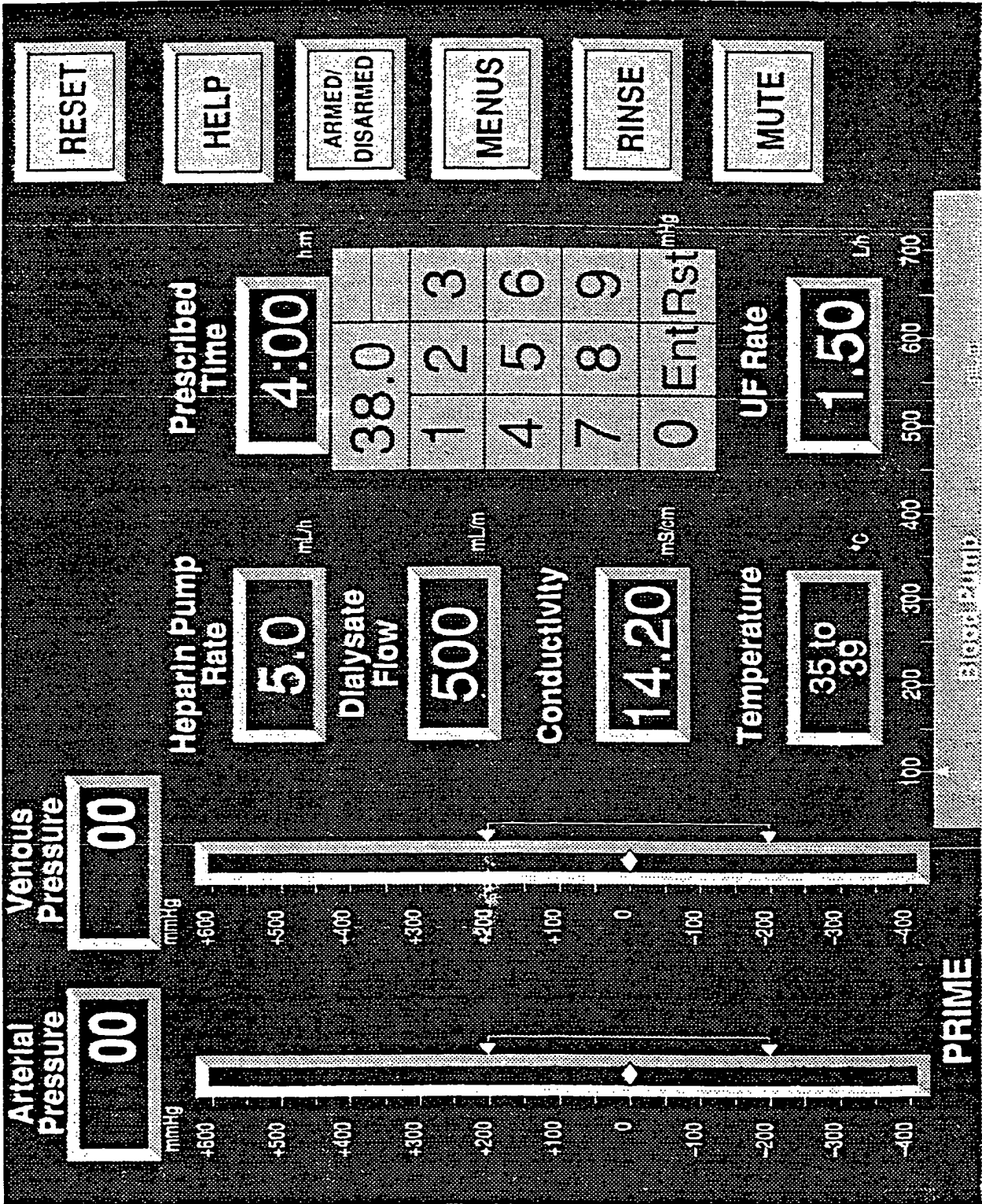
Drake Willock System 1000
Single Patient Delivery System
Operator's Manual
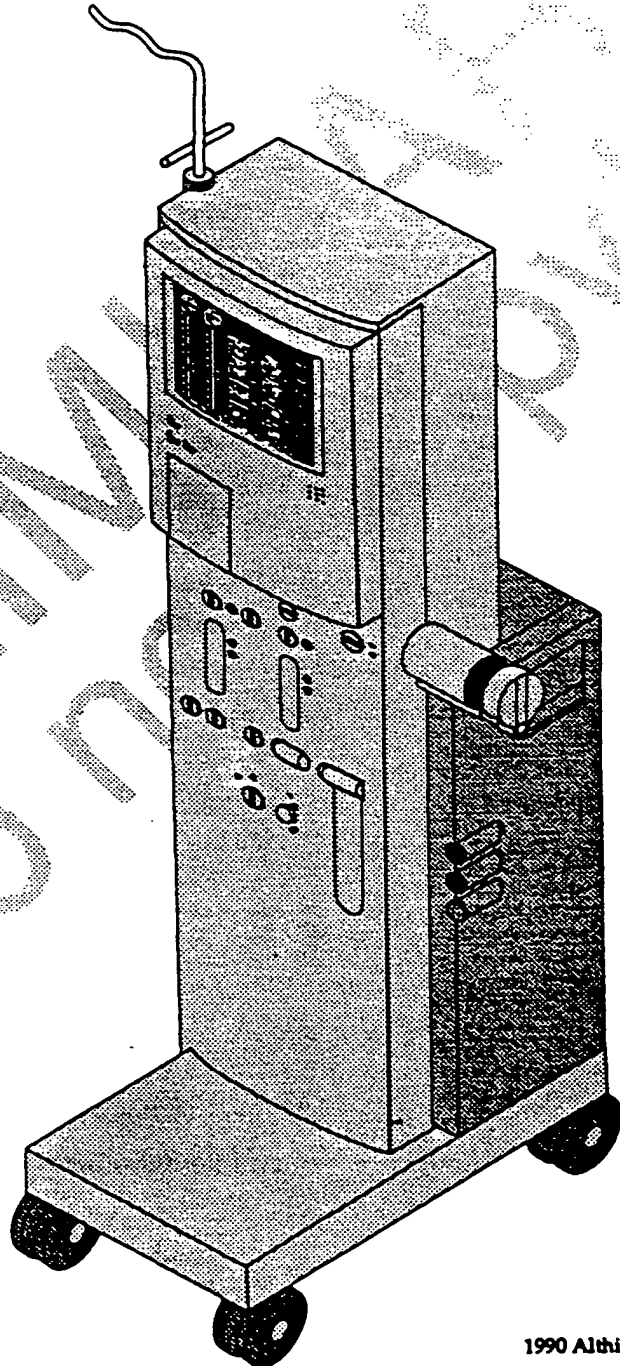
WARNING
This device is manufactured and intended for use only as prescribed by a physician. Modification, alteration, or lack of maintenance procedures as described in the labeling, may adversely affect the safety and efficacy of this device. The manufacturer is not responsible for malfunctions that compromise patient safety as a result of alteration, neglect, or misuse.

Replacement parts may vary from those shown in this manual. Should you have questions on those parts please contact Althin CD Medical, Inc.

The actual appearance of the machine may vary from the illustrations in this manual.

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Preliminary Draft

L2400-356 Rev. N 1/13/91

Table of Contents

Pr liminary Draft

Problem Solving

Reference

Appendix

Glossary
Machine Modes
Data Report Worksheet
UF Control Worksheet
Conversion Chart
Formaldehyde Warning Card
Checklist

Preliminary Draft

Introduction

Product Description

The Drake Willock ™ System 1000 Machine is a single-patient hemodialysis delivery system, which will provide dialysate at the prescribed temperature and ionic concentration to be used for hemodialysis treatment. It will have the ability to monitor machine, dialysate and blood circuit functions during dialysis. The machine is based on volumetric proportioning, volumetric ultrafiltration and digital electronics. The machine and treatment parameters are displayed on a CRT (video monitor). The operator control is done through a interactive touch screen which also makes the machine very easy to clean and use.

The machine has an automated self test prior to the start of each dialysis, this ensures that all of the essential monitoring and alarm functions of the machine are tested before each patient treatment. The automatic self test eliminates the risk that a busy clinician will forget to perform the required machine checks prior to each treatment.

One of the major problems with the dialysis treatments given today is the non-delivery of the prescription (e.g.; the patient is taken off treatment 5 minutes early, repeated alarms stop the blood pump or divert the dialysate to drain stopping the treatment). To enhance treatment quality assurance, the machine records essential treatment data such as treatment time. This treatment time clock stops when alarms interrupt dialysis by stopping the blood pump or bypassing the dialysate around the dialyzer. The data report allows the operator of the machine to know the precise time spent on dialysis enabling the clinician to determine if the dialysis prescription was delivered.

Prerequisites

The operator must:

- be proficient in the clinical application of hemodialysis and knowledgeable about the relevant physiology.

- be thoroughly trained and certified by the attending physician in the medical skills and knowledge required to operate this device and in providing the necessary patient treatment(s) normally associated with hemodialysis therapy.

- be thoroughly familiar with the contents of this manual and other operator's manuals that deal with the host machine and accessory devices that may be used with this device.

- be fully qualified and trained in the operation of this machine and able to distinguish normal from aberrant device behavior.

The System 1000 Single Patient Delivery System must:

- be in good working order and certified as such by the attending physician.

- be operated nly in accordance with the machine specifications listed by Althin CD Medical, Inc. and with the operating instructions contained within the System 1000 System Operator's

Manual and machine labeling. The attending physician is responsible for any changes to the procedures.

Indications

The System 1000 Single Patient Delivery System is indicated for use when a parallel flow dialyzer is chosen for use in chronic or acute hemodialysis treatments.

Contraindications

The System 1000 Single Patient Delivery System is not designed, sold or intended for any use except as indicated above. Furthermore, it is not intended to be used outside of the device specifications or limitations.

The System 1000 Single Patient Delivery System is not intended to be a substitute for the monitoring of the patient or of the patient's extracorporeal blood circuit by qualified personnel.

Product Improvement Policy

Drake Willock dialysis equipment was designed and built to the performance requirements stated in the product specifications.

It is the corporate policy to perform continuous product improvement research that often results in modifications to enhance patient safety or treatment effectiveness without incurring any obligation to make the same or similar changes to all equipment previously built and/or sold. When such improvements occur we will, from time to time, inform the owners of Drake Willock dialysis equipment and offer any available upgrades at reasonable prices. These upgrades, however, should not be construed as corrections of deficiencies, as the equipment met all the original product specifications when delivered.

Any product which, in the opinion of Althin CD Medical, Inc. proves not to have met product specifications will be remedied by us.

Should pre-owned Althin CD Medical equipment be purchased and reconditioned, the equipment should not be used until testing and analysis demonstrate that the equipment meets the original or upgraded specifications.

Technical Support

Althin CD Medical, Inc. offers technical support, technical training, consultation and machine service upon request. Contact your local Althin CD Medical service representative for additional information.

Operator's Manual

This manual provides the qualified operator with information necessary for the safe and efficacious operation of the System 1000 Single Patient Delivery System. The following summary of each section will give the operator an idea of where information is located in this manual.

Preliminary Draft

Introduction

The "Introduction" section gives the operator general information about the machine, its prerequisites, indications and contraindications.

Safety Summary

The "Safety Summary" section contains many of the general safety statements about the machine and its operation.

Components & Functions

The "Components & Functions" section familiarizes the operator with the names and use of the external controls and features.

Alarms

The "Alarms" section contains a summary of the machine alarms, visual and audible indicators and machine responses.

Machine Modes

The "Machine Modes" section contains a summary of the machine modes, visual indicators and machine actions.

Theory

The "Theory" section explains the basic operation of the machine.

Operation

The "Operation" section contains the recommended basic operation procedure for the machine.

Special Operations

The "Special Operations" section contains the detailed operational steps needed to use the specialized features of the machine.

Problem Solving

The "Problem Solving" section contains possible treatment problems and the recommended machine related operator actions.

Reference

The "Reference" section describes in detail the use of the control panel buttons and windows.

Appendix

The "Appendix" contains a glossary, the machine specifications and a UF control worksheet.

Preliminary Draft

Dialysate Temperature

The dialysate temperature may be set between 35.5 and 39°C. When the machine is turned on, the default temperature setting is 37°C.

To change the dialysate temperature:

a. Touch the TEMPERATURE display.

b. Use the keypad to input the desired dialysate temperature between 35.5 and 39°C.

c. Touch the keypad ENT button to enter the desired temperature as displayed in the keypad window.

If the previously set dialysate temperature is to be restored, touch the RST then ENT buttons.

Help Window

To view the help window:

a. Touch the HELP button.

To close the help window:

a. Touch the HELP or MAIN SCREEN button.

Data Report

To view the data report:

a. Touch the MENUS button.

b. Touch the DATA REPORT button.

To close the data report:

a. Touch the DATA REPORT or MAIN SCREEN button.

Disinfect Machine Fluid Pathway

Alternative disinfection methods are provided for disinfecting the fluid path. Althin CD Medical, Inc. recommends that regular cultures be taken of the dialysate to ensure that the bacterial level in the dialysate is acceptable.

With formaldehyde:

Supplies
- Gloves resistant to the disinfectant
- Formaldehyde (37% formaldehyde solution or "Formalin"), USP grade or better.

Preconditions
- The patient is disconnected from the dialyzer and blood lines.
- The machine is in rinse and has been rinsed for at least 10 minutes prior to infusing formaldehyde.

Procedure

WARNING: Be careful when handling formaldehyde. Read and f llow the instructions for the safe handling f formaldehyd n the warning label on the formaldehyde bottle and f llow ypur center's guidelines for use.

1. Connect the disinfect line (yellow connector) to a container of 37% formaldehyde.

2. Connect the acid/acetate concentrate line (pink connector) to the disinfect rinse port (yellow).

3. Infuse formaldehyde into the fluid path for approximately 15 minutes.

4. Obtain a sample of the disinfect solution from the drain line. Make sure that formaldehyde is present in the sample before going on to the next step.

5. Disconnect the machine from the formaldehyde supply.

   To disconnect the machine:

   a. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

   b. Wait approximately 15 seconds for the disinfect line to drain, then connect the disinfect line (yellow connector) to the disinfect rinse port (yellow).

6. Turn off the machine.

   To turn off the machine, press the power switch. Turn off the mains switch at night.

7. Label the machine with a formaldehyde warning sign on which the date and time have been recorded.

8. Turn off the water.

WARNING: Formaldehyde must remain in the fluidpath for at least two hours for adequate disinfection.

With sodium hypochlorite (bleach):

Supplies
- Gloves resistant to the disinfectant
- 1.75% solution of sodium hypochlorite

  Dilute one part household bleach (4 to 6% sodium hypochlorite) with two parts filtered water. This solution should be capped and labeled. This bleach mixture should only be kept for two days and stored in a cool, dark place. Approximately 200 ml of diluted bleach are required each time this procedure is performed.

Preconditions
- The patient is disconnected from the dialyzer and blood lines.
- The machine is in rinse and has been rinsed for at least 10 minutes prior to infusing bleach.

Procedure

1. Connect the disinfect line (yell w connector) to a container of 200 ml of 1.75% bleach solution.

Preliminary Draft

2. C nnect the acid/acetate concentrate line (pink connector) to the disinfect rinse port (yell w).

3. Allow diluted bleach to infuse into the fluid path for 15 minutes.

4. After the 15 minutes, disconnect the machine from the bleach supply.

   To disconnect the machine:

   a. Connect the acid/acetate concentrate line (pink connector) to th acid/acetate rinse port (pink).

   b. Wait approximately 15 seconds for the disinfect line to drain, then connect the disinfect line (yellow connector) to the disinfect rinse port (yellow).

6. Rinse the machine until it is free of bleach.

7. After 15 minutes, obtain a sample of the rinse solution and check for residual sodium hypochlorite.

   a. Check for residual bleach content with a test specific for sodium hypochlorite.

   b. If the residual bleach content is within acceptable limits, the machine can be prepared for dialysis. If the machine is not within acceptable limits continue to rinse the machine until the level is acceptable.

WARNING: **Make sure that the determination test shows a sufficiently low level of disinfectant in the rinse solution before dialysis. Refer to the attending physician's directives for the acceptable limit and the AAMI standard for hemodialysis.**

To ensure that the disinfectant level in the dialyzer circuit is below a level acceptable for patient safety, sample the rinse solution in the dialysate lines.

Make sure that the determination test is specific for the disinfectant used.

Note: If the machine is to remain idle for an extended period of time, keep the machine rinsing until beginning preparation for dialysis.

With Actril® solution:

Supplies
- Gloves resistant to the disinfectant
- Actril® solution, approximately 200 ml
  - Trademark of Renal Systems
- Actril residual test strips
- Actril Relative indicator strips

Preconditions -
- The patient is disconnected from the dialyzer and blood lines.
- The machine is in rinse and has been rinsed for at least 10 minutes prior to infusing a disinfectant.

Procedure

WARNING: **Be careful when handling disinfectants. R ad and f ll w the instructions f r the safe handling of disinfectants n the warning label n the bottl .**

1. C nnect the disinfect line (yell w connecto) to a container of Actril soluti n.

   Refer to the disinfectant labeling for detailed instructions.

2. Connect the acid/acetate concentrate line (pink connector) to the disinfect rinse port (yellow).

3. Infuse disinfectant into the fluid path for approximately 15 minutes.

4. Test for the presence of Actril at the drain line.

   a. Take a sample from the drain line.

   b. Test the sample using the directions given on the Actril Relative Indicator Test Strips container.

   c. Continue infusing Actril solution as required.

5. After the needed infusion, turn off the machine.

6. Disconnect the machine from the Actril supply.

   To disconnect the machine:

   a. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

   b. Wait approximately 15 seconds for the disinfect line to drain, then connect the disinfect line (yellow connector) to the disinfect rinse port (yellow).

7. Label the machine with a disinfectant warning sign on which the date, time and type of disinfectant have been recorded.

8. Allow the Actril solution to remain in the fluid pathway for at least 30 minutes.

WARNING: **Make sure that the disinfectant remains in the fluid pathway long enough for adequate disinfection. Refer to the chemical disinfectant manufacturer's labeling for detailed information.**

9. Before the next use, rinse the fluid pathway for at least 10 minutes with water.

10. Test a dialyzer circuit sample of rinse solution for the presence of Actril.

    a. Withdraw a sample of the rinse solution from the dialyzer circuit.

    b. Test the sample for residual disinfectant using Actril Residual Test Strips. Refer to the Actril labeling for detailed actions.

WARNING: **Make sure that the determination test shows a sufficiently low level of disinfectant in the rinse solution before dialysis. Refer to the attending physician's directives for the acceptable limit, the chemical disinfectant manufacturer's labeling and the AAMI standard for hemodialysis.**

To ensure that the disinfectant level in the dialyzer circuit is below a level acceptable for patient safety, sample the rinse soluti n in the dialysate lines.

Make sure that the determination test is specific for the disinfectant used.

Safety Summary

This summary does not contain all the safety statements in this manual. Other advisories, cautions and warnings are included within the manual text.

Advisories

An ADVISORY is a statement identifying conditions or practices that could result in misapplication of the therapy.

Cautions

A CAUTION is a statement identifying conditions or practices that could result in equipment or other property damage.

Warnings

A WARNING is a statement identifying conditions or practices that could result in personal injury or loss of life.

WARNING: Do:

- read and follow the operator's manual prior to operating this machine.

- keep this and other associated manuals readily availabl for use by new operators or qualified service personnel.

- use the proper power cord.

- make sure that the wheels are unlocked before attempting to move the machine.

- perform regular maintenance as described in the maintenance manual to ensure patient safety.

- keep your fingers out of the line clamp.

WARNING: Do Not:

- under any circumstances perform any testing or maintenance of this machine while dialysis is in progress.

- cut or remove the grounding contact from the plug.

- use any adapter device on the power cord for the purpose of plugging into a non-grounded power source.

- use an extension cord.

- remove covers or panels when the machine is connected t a power source.

- operate the machine without covers and panels properly installed.

- remove any caution, warning or other descriptive labels from the machine.

- operate this machin in an explosive envir nment or near flammabl anesthetics.

- d n t use the IV pole t m v the machine.

Warnings and Notes Regarding Concentrates

1. It is important to know the expected conductivity of the dialysate made from the particular concentrates(s) being used.

2. If concentrates are prepared from dry chemicals, be sure the chemicals are thoroughly dissolved before using the concentrates. Make sure that the water used to prepare the concentrate at least conforms to the AAMI standards for water used in hemodialysis. It is recommended that the water be especially low in contaminants and pyrogenic material.

3. Use good quality concentrates, the better quality concentrates often dissolve faster and are easier to mix. The potential for precipitate formation is reduced with concentrates that mix correctly. Significant variations in quality have been reported in concentrates from different major manufacturers.

WARNING: 1. **Make sure the correct concentrate is used for the dialysis and that the concentrate containers connected to the machine contain an adequate amount of concentrate(s) for the entire dialysis, including setup and shutdown.**

2. **Do not dialyze using acid concentrate alone.**

3. **Make sure that the concentrate containers are labeled regarding contents.**

4. **For correct proportioning, the concentrate lines must be connected to the correct machine fitting and/or concentrate containers.**

Notes Regarding Water

The water supply entering the system should at least conform to the AAMI standards for water used in hemodialysis. It is recommended that the water be especially low in contaminants and pyrogenic material. This recommendation also applies to any concentrates used with the system, particularly bicarbonate concentrates which many facilities mix themselves. It is the responsibility of the attending physician in the clinic to evaluate the purity of the water supply and concentrates against any potential risk to the patient under the intended conditions of dialysis.

Preliminary Draft

Components & Functions

This section of the manual identifies the components and describes their functions. The operator should become thoroughly familiar with this section prior to operating the machine.

Note: Words in bold **CAPITAL LETTERS** denote specific labels on the machine.
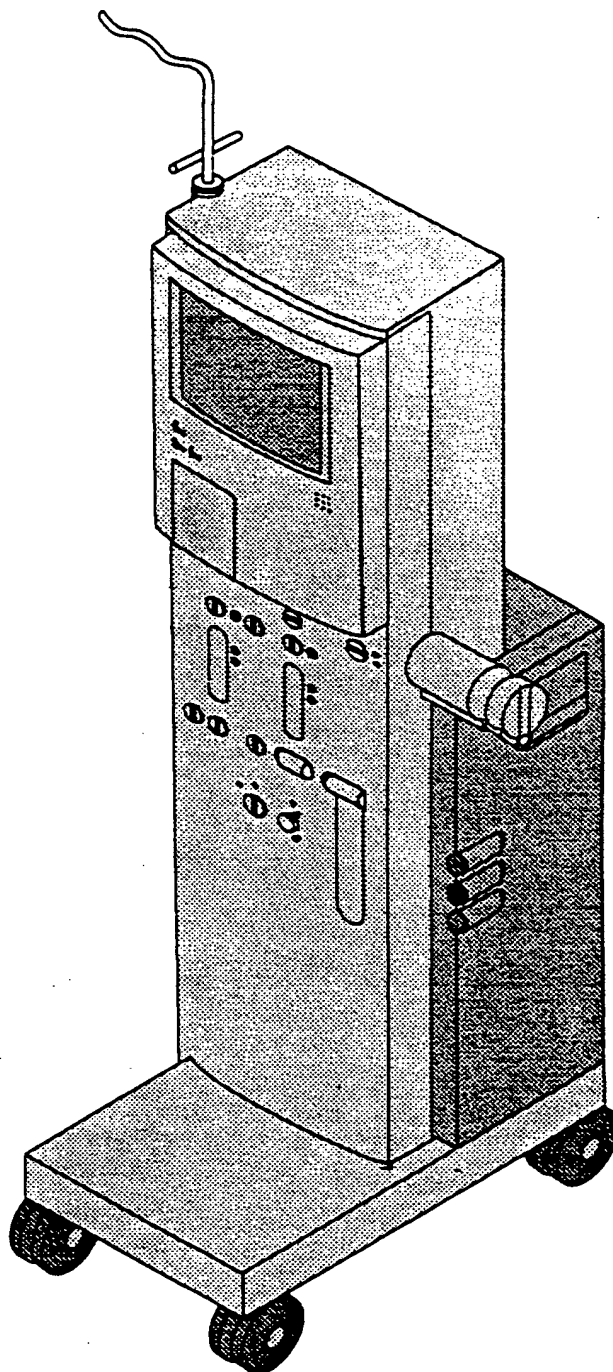
Front

Main alarm lamp

> Flashes when operator input or assistance is needed at the machine. Flashes during the machine alarms (Alarm Mode), the Standby Mode, the Prime Mode and the Rinse Mode when the conductivity and temperature are within the normal operating range (i.e., between the high and low alarm limits).

Video screen and touch panel

> Display machine functions and controls. The operator controls operating parameters of the machine by touching specific areas of the screen.

IV pole knob

> Adjusts the height of the IV pole.

Blood pump

> Controls the extracorporeal blood flow.

Pressure luers

> Accept the pressure monitoring line from the drip chambers.

Level adjust buttons

> Raise or lower the liquid level in the drip chamber.

Air detector

> Detects the presence of air in the venous blood line.

Line clamp

> Clamps the venous blood line during an extracorporeal alarm and during a power failure.

Dialyzer holder

> Holds the dialyzer. The dialyzer holder rotates to facilitate dialyzer priming.

Heparin pump

> Infuses an operator-adjustable amount of heparin into the extracorporeal circuit over a period of time or by a bolus. The heparin pump stops when the blood pump is stopped.
>
> Uses a 10 or 20 ml capacity syringe. The syringe the machine is calibrated for is listed in the data report.
>
> The heparin pump may be turned off by setting the heparin pump rate to 0 ml/h.
>
> The heparin pump stops during an extracorporeal alarm or when the blood pump is turned off manually.

Pr liminary Draft

Main alarm lamp

Vid   screen and touch panel

IV pole knob

Blood pump

Venous pressure luer

Arterial pressure luer

Dialyzer holder

Arterial level
adjust buttons

Venous level
adjust buttons

Heparin pump

Air detector

Line clamp
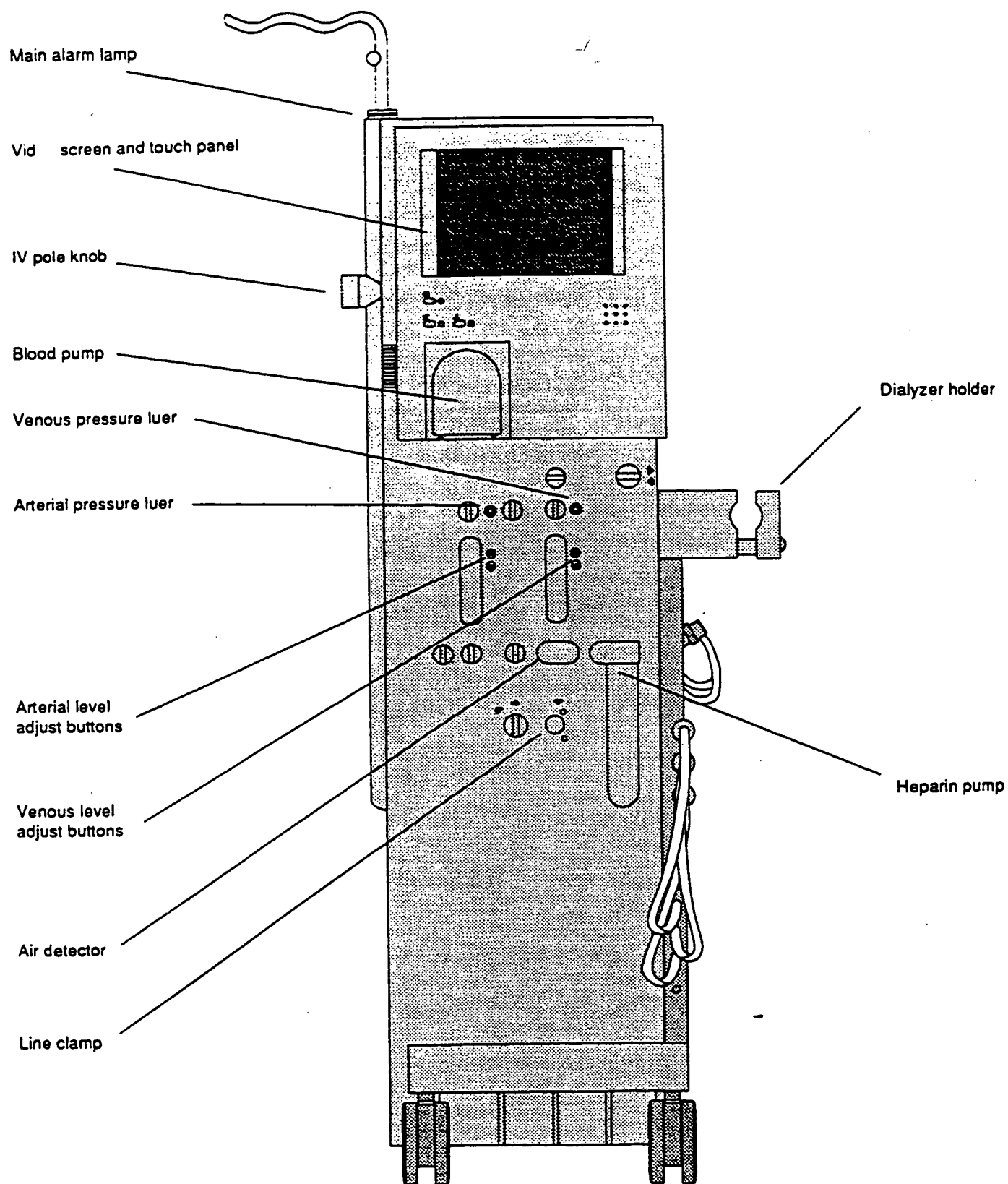
P wer switch and lamp

Turns the machine on and off. The lamp lights when power is on.

Blood pump switch and lamp

Turns the blood pump on and off. The lamp lights when power is on.

Manual bypass switch and lamp

During dialysis, stops the flow of dialysate through the dialysate lines for sequential ultrafiltration.

During setup and shutdown, stops the flow of dialysate through the dialysate lines for connection to the dialyzer or machine.

The lamp flashes when the machine is in manual bypass.

If the manual bypass button has been pressed, while in the Rinse Mode, the machine will remain in manual bypass for approximately 1 minute. At the end of the minute, the flow resumes in the "dialyzer circuit" and the manual bypass lamp goes off.

Blood line clips

Hold the blood lines in an orderly arrangement.

Preliminary Draft

Power switch
and lamp

Blood pump switch
and lamp

Manual bypass
switch and lamp

Blood line clips

Pr liminary Draft
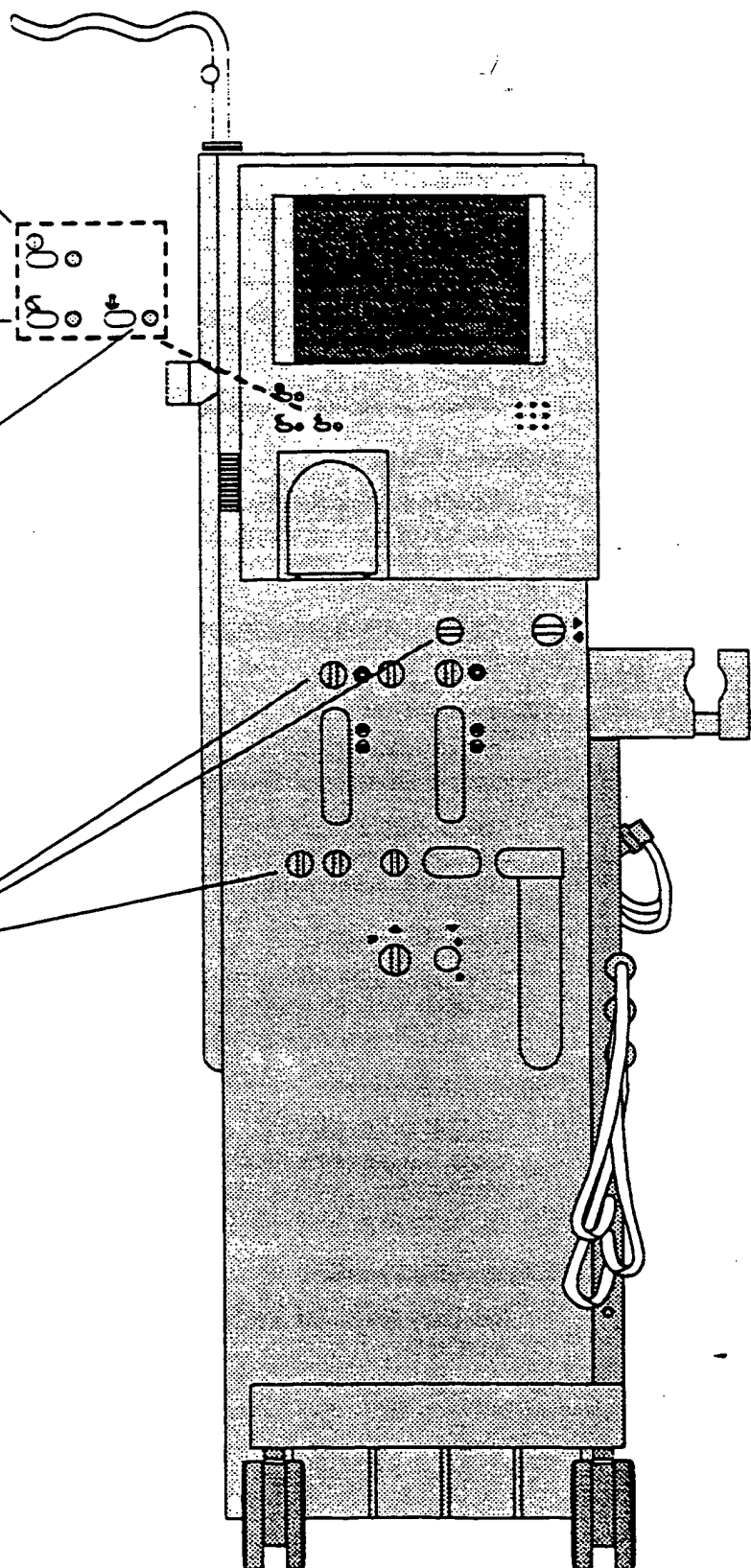
Video Screen and Touch Panel

Buttons

> Touch sensitive areas used by the operator to control machine operation.

> The function and displayed name of individual buttons may change with the machine operating mode.

> Some buttons appear only when they are needed. Refer to the "Reference" section for detailed information.

Pulse spot

> Flashes to indicate that the screen (control panel) is active.

Bulletin window

> Displays messages about unusual operational or machine errors, such as the blood pump stop alarm.

Instructions window

> Displays messages to assist the operator in operating the machine.

Alarm window

> Displays alarms, that are not monitored elsewhere on the screen. Also displays some operator messages.

> Alarms displayed in this window include blood leak, air detector, bypass fail and no dialysate flow. Operator messages displayed in this window include rinse interlock information.

Machine status area

> Displays the operating mode and/or machine status such as POWER ON, STANDBY, RINSE, SELF TEST, PRIME, DIALYZE, ALARM and SHUTDOWN.

Monitor windows

> Display the value of the monitored function. The monitor windows, except ARTERIAL PRESSURE and VENOUS PRESSURE, also are touch sensitive areas used by the operator to control machine operation.

Blood pump display

> Indicates the blood pump speed and whether the blood pump is on or off.

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Buttons

Pulse spot

Bulletin window

Instruction window

Alarm window

Monitor window

Machine status area

Blood pump display

Arterial Pressure	Venous Pressure
-14	+54
mmHg	mmHg

RESET

BP MONITOR

SET LIMITS

MENUS

RINSE

MUTE

Rate	Time
5.0 mLh	:30 hm

Dialysate Flow	UF Removed
500 mLm	.75 L

Conductivity	TMP
14.20 mScm	55 mmHg

Temperature	UF Rate
38.0 ℃	1.50 Lh

DIALYZE

100   200   300   400   500   600   700

Off   Blood Pump   ## mLm
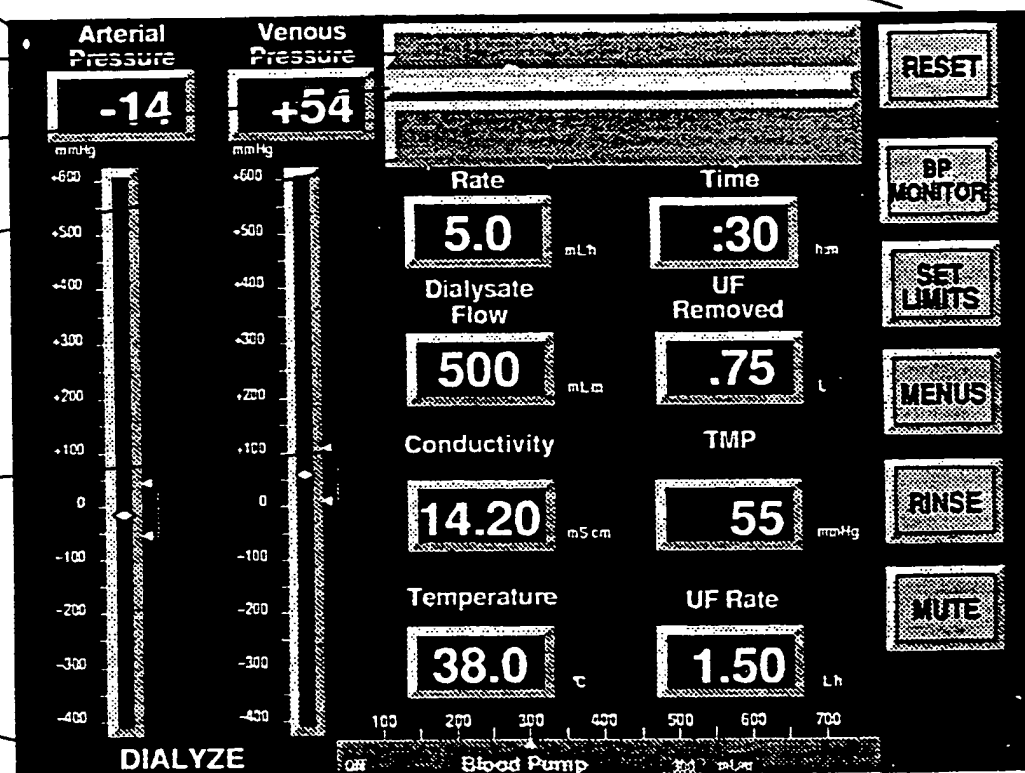
Main Screen

Alarm indicat rs

Flash to indicate which alarm has occurred. When a monitor is in alarm, a flashing pointer appears beside the monitor window, and the alarm window flashes. For air detector and blood leak alarms, the alarm message appears in the alarm window and the alarm window flashes.

Arterial and venous pressure alarm limit indicators

Are pointers indicating the upper and lower arterial and venous pressure alarm limits.

Help window

Displays a brief statement of the use of available buttons.

Keypad

Is used by the operator to input data into the machine to set the prescribed treatment time, target fluid loss, manual UF rate, heparin pump rate, and dialysate temperature.

Preliminary Draft
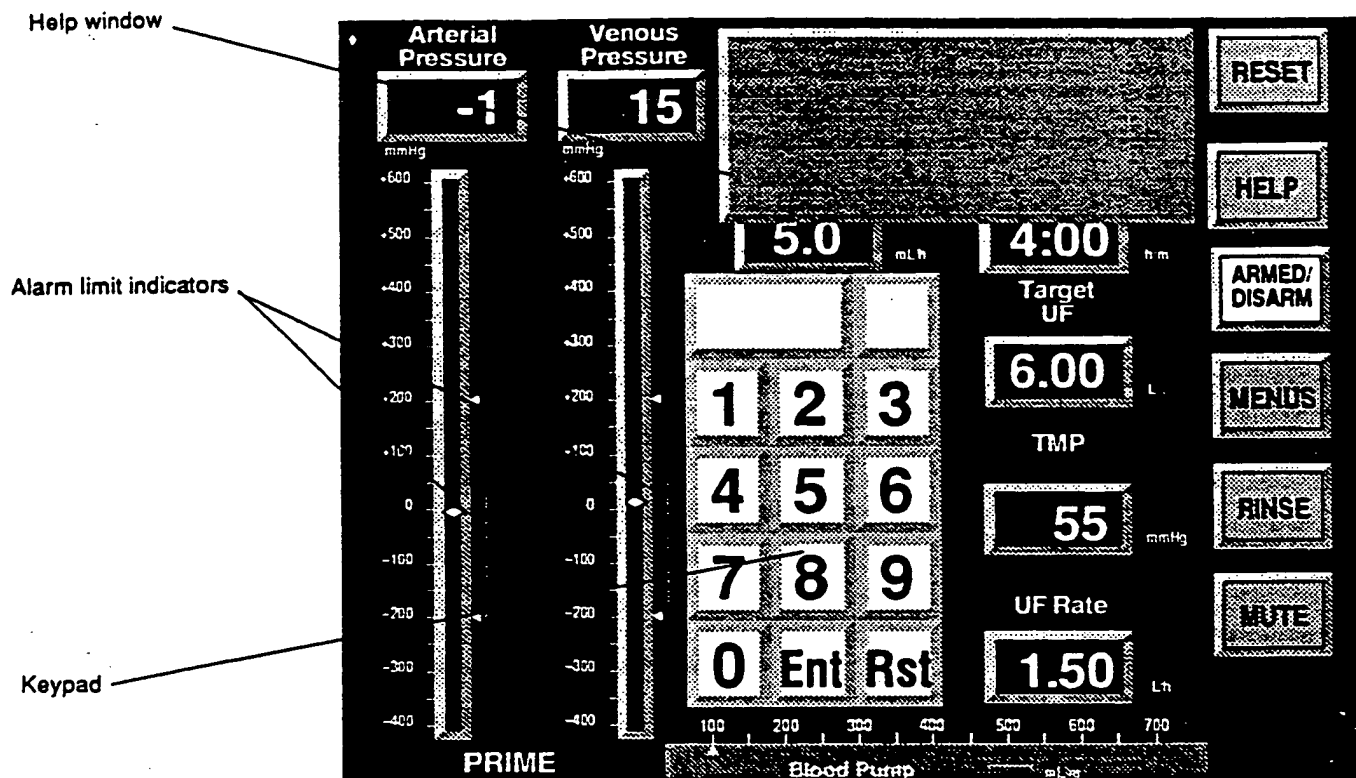
Main Screen

Right Side

Acid/acetate rinse port (pink/red)

During rinse and storage, accepts the acid/acetate concentrate line connector (pink).

The acid/acetate rinse port and concentrate line fitting are keyed and color-coded to prevent accidental insertion bicarbonate concentrate or chemical disinfect line connectors.

Acid/acetate concentrate line (with pink/red connector)

During acetate dialysis, delivers acetate concentrate from the acetate concentrate jug to the machine.

During bicarbonate dialysis, delivers acid concentrate from the acid concentrate jug to the machine.

During rinse and storage, is connected to the acid/acetate rinse port (pink).

During chemical disinfect, is connected to the disinfect port (yellow).

Bicarbonate concentrate line (with blue connector)

During bicarbonate dialysis, delivers bicarbonate concentrate from the bicarbonate concentrate jug to the machine.

During acetate dialysis, rinse, storage and chemical disinfect, is connected to the bicarbonate rinse port (blue).

Bicarbonate rinse port (blue)

During rinse, chemical disinfection and acetate dialysis; accepts the bicarbonate concentrate line connector (blue).

Is keyed and color coded to prevent accidental insertion of the acid/acetate concentrate or disinfectant line connector.

Disinfect line (with yellow connector)

During chemical disinfect, delivers disinfectant from the disinfectant container to the machine.

During acetate dialysis, bicarbonate dialysis and rinse, is connected to the disinfect port (yellow).

Disinfect rinse port (yellow)

During chemical disinfection, accepts the acid/acetate concentrate line (pink).

During rinse and dialysis, accepts the disinfectant line (yellow).

Dialysate line connector holders (rinse block)

Accepts the dialysate line connectors when the machine is stored, rinsed, cleaned or disinfected.

Preliminary Draft

Disinfect Machine Fluid Pathway

With formaldehyde:

1. Connect the disinfect line (yellow connector) to a container of 37% formaldehyde.

2. Connect the acid/acetate concentrate line (pink connector) to the disinfect rinse port (yellow).

3. Infuse formaldehyde into the fluid path for approximately 15 minutes.

4. Obtain a sample of the disinfect solution from the drain line. Make sure that formaldehyde is present in the sample before going on to the next step.

5. Disconnect the machine from the formaldehyde supply.

   a. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

   b. Allow the disinfect line to drain, then connect the disinfect line (yellow connector) to the disinfect rinse port (yellow).

6. Turn off the machine.

7. Label the machine with a formaldehyde warning sign on which the date and time have been recorded.

8. Turn off the water.

With sodium hypochlorite (bleach):

1. Connect the disinfect line (yellow connector) to a container of 200 mL of 1.75% bleach solution.

2. Connect the acid/acetate concentrate line (pink connector) to the disinfect rinse port (yellow).

3. Allow diluted bleach to infuse into the fluid path for 15 minutes.

4. After the 15 minutes, rinse the disinfect line for approximately 2 minutes.

5. After the two minutes, disconnect the machine from the bleach supply.

   a. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

   b. Allow the disinfect line to drain, then connect the disinfect line (yellow connector) to the disinfect rinse port (yellow).

6. Rinse the machine until it is free of bleach.

7. After 15 minutes, obtain a sample of the rinse solution and check for residual sodium hypochlorite.

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Discontinue Dialysis

1. Discontinue dialysis.

   N te: If a minimum UF rat (oth r than zero) is desired for returning th patient's blood after the target UF is reached:

   a. Enter a new Target UF higher than the current UF removed.

   b. *Immediately* enter the specific manual UF rate desired.

2. Record the treatment data from the data report before initiating rinse.

3. Disconnect the dialysate lines from the dialyzer and connect them to the machine rinse block.

Prepare Machine for Another Patient (if required) (Patient disconnected)

1. Initiate the Rinse Mode.

2. Make sure there is an adequate supply of concentrate(s) in the containers(s) for the entire dialysis treatment including setup.

3. Continue the predialysis preparation by completing Rinse Machine (Before Dialysis) steps 10 through 15.

Rinse Machine (After Dialysis) (Patient disconnected)

1. Connect the concentrate lines to the machine.

   After <u>acetate</u> dialysis:

   a. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

   After <u>bicarbonate</u> dialysis:

   a. Connect the bicarbonate concentrate line (blue connector) to the bicarbonate rinse port (blue).

   b. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

2. Initiate the Rinse Mode.

3. Rinse the machine with water for 10 minutes.

4. If the machine is to be disinfected, refer to Disinfect Machine Fluid Pathway in the Special Operations section of this manual.

   If the machine is to be turned off, go to step 5.

5. Turn off the machine.

6. Turn off the water supply.

Pr liminary Draft

b. Touch the RESET button, as required.

c. Set the blood pump flow rate.

d. Turn on the blood pump, as required.

To connect the dialyzer connectors to the dialyzer:

a. Press the manual bypass button.

b. Connect the dialyzer connectors to the appropriate dialyzer ports.

c. Press the manual bypass button.

To load the heparin pump:

a. Fill the syringe with heparin.

b. Connect the heparin line to the syringe.

c. Clamp the heparin line but do not prime the line.

14. Set the treatment parameters; i.e., prescribed dialysis time and desired fluid loss.

15. Turn off the blood pump, as required.

Start Dialysis

Note: If an extracorporeal alarm exists, clear and reset the alarm before touching the START button.

1. Touch the START button (button #5).

   Note: If a UF rate lower than the calculated rate is desired at treatment initiation, enter a low manual UF rate before turning on the blood pump. Otherwise the calculated UF rate will start as soon as the blood pump starts.

   To initiate heparin infusion:

a. With the blood pump on, give a heparin bolus.

b. Unclamp the heparin line.

c. Set the heparin infusion rate.

Drake Willock System 1000 Single Patient Delivery System

Pre-Setup

- The patient is disconnected from the blood lines and dialyzer.
- The machine is connected to the water supply and the water is off.
- The drain line is in the drain.
- The power cord is plugged in and the mains power switch is on.
- The front panel power switch is off.
- The acid/acetate concentrate line (pink connector) is connected to the acid/acetate rinse port (pink).
- The bicarbonate concentrate line (blue connector) is connected to the bicarbonate rinse port (blue).
- The dialysate lines (yellow connector) are connected to the rinse port (yellow).

Rinse Machine (Before Dialysis)

1. Turn on the water supply.

2. Turn on the machine.

3. Initiate the Rinse Mode.

   Touch RINSE button, then touch RINSE VERIFY button.

4. Touch RESET button as required.

5. If the machine had no disinfectant in the fluid path and is to be disinfected, go to step 6.

   If the machine had formaldehyde or another disinfectant in the fluid path, go to step 7.

6. Disinfect the fluid path, as required.

7. Rinse the disinfectant from the fluid path, as required.

8. Test the rinse solution for residual disinfectant, as required.

9. Connect the concentrate(s).

   For acetate dialysis:

   a. Connect the acid/acetate concentrate line (pink connector) to a full container of acetate concentrate.

   For bicarbonate dialysis:

   a. Connect the acid/acetate concentrate line (pink connector) to a full container of acid concentrate.

   b. Connect the bicarbonate concentrate line (blue connector) to a full container of bicarbonate concentrate.

10. After the conductivity and temperature stabilize, initiate the Self Test Mode.

    Touch the TEST button.

    Note: If there are any extracorporeal alarms, touch the RESET button to clear the alarms and access the TEST button.

    Do not manually turn on the blood pump during Self Test or a blood pump overspeed alarm will occur.

    Make sure the machine is not in manual bypass or the Self Test will fail. _

    Test the dialysate.

11. Set up the dialyzer and blood lines, as required.

12. Initiate Prime, touch the PRIME button.

13. Prime the dialyzer and blood lines.

    a. Touch the ARMED / DISARM button to disarm the extracorporeal alarms.

Pound	Kilogram	Milliliter
11	5	5000
12	5.45	5450
13	5.91	5910
14	6.36	6360
15	6.82	6820
16	7.27	7270
17	7.73	7730
18	8.18	8180
19	8.64	8640
20	9.09	9090
21	9.45	9450
22	10	10000
23	10.45	10450
24	10.91	10910
25	11.36	11360
26	11.80	11800
27	12.26	12260
28	12.71	12710
29	13.17	13170
30	13.62	13620
31	14.07	14070
32	14.53	14530
33	14.98	14980
34	15.44	15440
35	15.89	15890

Pound	Kilogram	Milliliter
36	16.34	16340
37	16.80	16800
38	17.25	17250
39	17.71	17710
40	18.16	18160
41	18.61	18610
42	19.07	19070
43	19.52	19520
44	19.98	19980
45	20.43	20430

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Conversion Chart – Pounds to Kilograms to Milliliters

Pound	Kilogram	Milliliter		Pound	Kilogram	Milliliter
1/4	.11	110		6	2.73	2730
1/2	.23	230		6 1/4	2.84	2840
3/4	.34	340		6 1/2	2.95	2950
				6 3/4	3.07	3070
1	.45	450		7	3.18	3180
1 1/4	.57	570		7 1/4	3.30	3300
1 1/2	.68	680		7 1/2	3.41	3410
1 3/4	.80	800		7 3/4	3.52	3520
2	.91	910		8	3.64	3640
2 1/4	1.02	1020		8 1/4	3.75	3750
2 1/2	1.14	1140		8 1/2	3.86	3860
2 3/4	1.25	1250		8 3/4	3.98	3980
3	1.36	1360		9	4.09	4090
3 1/4	1.48	1480		9 1/4	4.20	4200
3 1/2	1.59	1590		9 1/2	4.32	4320
3 3/4	1.70	1700		9 3/4	4.43	4430
4	1.82	1820		10	4.55	4550
4 1/4	1.93	1930		10 1/4	4.66	4660
4 1/2	2.05	2050		10 1/2	4.77	4770
4 3/4	2.16	2160		10 3/4	4.89	4890
5	2.27	2270				
5 1/4	2.39	2390				
5 1/2	2.5	2500				
5 3/4	2.61	2610				

Fluid Removal Analysis

(Optional aft r dialysis.)

Find actual fluid removed:

Pre dialysis weight (from scale) _____ lb ÷ 2.2 = _____ kg x 1000 = _____ ml

+ Priming saline intake (actual) _____ ml

+ P.O. intake (actual) _____ ml

+ I.V. fluid intake (actual) _____ ml

+ Rinseback saline (actual) _____ ml

= Subtotal _____ ml

− Output during dialysis (urine, emesis, etc.) _____ ml

= Total actual pre dialysis weight (subtotal) _____ ml ÷ 1000 = _____ L

Post dialysis weight (from scale) _____ lb ÷ 2.2 = _____ kg = _____ L

− Solid food intake _____ kg = _____ L

= Total adjusted post dialysis weight (subtotal) _____ L

Total actual pre dialysis weight (from above) _____ L

− Total adjusted post dialysis weight (from above) _____ L

= Actual volume removed (total) _____ L

UF Control Worksheet

Patient: _____ Date:_____

Find weight to remove:

    Pre dialysis weight   _____ lb or   _____ kg

− Desired weight   _____ lb or   _____ kg

= Desired weight to remove _____ lb ÷ 2.2 _____ kg

Find volume to remove:

    Desired weight to remove _____ kg x 1000 = _____ ml

+ Priming saline intake   _____ ml

+ P.O. intake (add foods which have high water content only)   _____ ml

+ I.V. fluid intake   _____ ml

+ Rinseback saline intake   _____ ml

= Total volume to remove   _____ ml ÷ 1000 = _____ L

Data Report Worksheet

Patient _____ Date _____

Prescribed Treatment Time   =   _____ h:m

Elapsed Treatment Time   =   _____ h:m

Treatment Time Remaining   =   _____ h:m

Target UF   =   _____ L

UF Removed   =   _____ L

UF Remaining   =   _____ L

Total Blood Processed   =   _____ L

Total Infused Heparin   =   _____ ml

Syringe _____   Bolus _____ ml

UF rate

Concentrate   ❏ Acetate   ❏ Bicarbonate

Calculated UF rate has been overridden.   ❏ yes   ❏ no

Data Report Worksheet

Patient _____ Date _____

Prescribed Treatment Time   =   _____   h:m

Elapsed Treatment Time   =   _____   h:m

Treatment Time Remaining   =   _____   h:m

Target UF   =   _____   L

UF Removed   =   _____   L

UF Remaining   =   _____   L

Total Blood Processed   =   _____   L

Total Infused Heparin   =   _____   ml

Syringe _____   Bolus _____ ml

UF rate

Concentrate   ❑ Acetate   ❑ Bicarbonate

Calculated UF rate has been overridden.   ❑ yes   ❑ no

Machine Mode Matrix

Mode	Machine status area displays	Machine action
power on	POWER ON	• The machine is powering up. The electrical circuits are energizing. The electrical circuits are warming up.
standby	STANDBY	• The main alarm lamp flashes. • The blood pump will not operate. • The line clamp is clamped. • The audio alarm sounds. • The machine is in bypass. • The heparin pump is stopped. • The UF rate is automatically set at 0 L/h (off).

rinse	RINSE	• The dialyzer connectors *must* be on rinse block to start rinse.
		• The blood pump will:
		  – operate if the dialyzer connectors remain on the rinse block.
		  – not operate if the dialyzer connectors are removed from the rinse block.
		• The line clamp will:
		  – remain open if the dialyzer connectors remain on the rinse block.
		  – clamp if the dialyzer connectors are removed from the rinse block.
		• The UF rate is automatically set at 3.60 L/h.
		• Pressures between flow equalizer cavities are relieved so excessive vacuum does not develop in the flow path.
		• The bypass valve cycles into bypass for 5 seconds every minute.
		• Concentrate may be introduced into the fluid path. (Proportioning ratio is determined by acid/acetate and bicarbonate rinse port interlocks.)
		• Air detector and blood leak detector machine responses (other than the visual alarm indicator) are disabled.
		• The arterial pressure alarm limits are –400 and +600 mmHg.
		• The venous pressure alarm limits are ±200 mmHg around the indicated venous pressure approximately 10 seconds after the blood pump turned on, off or rate changed.
		• The TMP alarm limits are ±200 mmHg around the indicated TMP approximately 1 minute after the UF rate is changed or the blood pump is turned on, off or rate changed.
		• The audio alarm inhibited except for a no supply alarm, an arterial pressure alarm, a venous pressure alarm, or power failure alarm.
		• If manual bypass has been selected, the machine will remain in manual bypass for no more than 1 minute.

Mode	Machine status window displays	Machine action
rinse with conductivity and temperature in operating range	RINSE	• The audio alarm will beep 3 times. • The main alarm lamp flashes. • The dialyzer connectors *must be* on rinse block to start rinse. • The blood pump will: – operate if the dialyzer connectors remain on the rinse block. – not operate if the dialyzer connectors are removed from the rinse block. • The line clamp will: – remain open if the dialyzer connectors remain on the rinse block. – clamp if the dialyzer connectors are removed from the rinse block. • The UF rate is automatically set at 3.60 L/h. • Pressures between flow equalizer cavities are relieved so excessive vacuum does not develop in the flow path. • The bypass valve cycles into bypass for 5 seconds every minute. • Concentrate may be introduced into the fluid path. • Air detector and blood leak detector machine responses (other than the visual alarm indicator) are disabled. • The arterial pressure alarm limits are –400 and +600 mmHg. • The venous pressure alarm limits are ±200 mmHg around the indicated venous pressure 10 seconds after the blood pump turned on, off or rate changed. • The TMP alarm limits are ±200 mmHg around the indicated TMP approximately 1 minute after the UF rate is changed or the blood pump is turned on, off or rate changed. • The audio alarm inhibited except for a no supply alarm, an arterial pressure alarm, a venous pressure alarm, or power failure alarm. • If manual bypass has been selected, the machine will remain in manual bypass for no more than 1 minute.
self test	SELF TEST	• Proportioning ratio as determined by acid/acetate and bicarbonate rinse port interlocks is set. • The data report is cleared. • The blood pump will automatically turn on and off. • The line clamp will automatically clamp and unclamp. • The primary conductivity alarm limits are set to ±5% around the dialysate conductivity, which has been verified against an external calibrated conductivity meter. • The audio alarm beeps 2 times to prompt the operator to verify conductivity. • The audio alarm beeps 3 times to prompt the operator if the test failed. The following functions are tested during self test: • Venous and arterial pressure test – Operator prompt appearing in the instruction window: BLOOD PRESSURE TEST: ARE PRESSURE LUERS PLUGGED?

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Mode

Machine status window displays

Machine action

- Venous high low pressure alarm
- Operator prompt appearing in the instruction window: VERIFY AUDIO ALARM/ALARM LAMP?
- Blood pump stops during an extracorporeal alarm
- Arterial high pressure alarm
- Arterial and venous pressure accuracy
- Venous low pressure alarm
- Arterial low pressure alarm
• Blood leak alarm
• UF system test
- UF system checked for leaks
- UF metering device functionality
• TMP test
- TMP calculation
- TMP stability
- TMP high pressure alarm
- TMP low pressure alarm
• Temperature test
- Primary high temperature alarm
- Primary low temperature alarm
- Redundant high temperature high alarm
- Temperature stability
• Conductivity test
- Simulated high conductivity/high temperature alarm
- Primary high conductivity high limit
- Primary low conductivity alarm limit
- Redundant high conductivity high limit
- Redundant low conductivity alarm limit
- Backup high conductivity high limit
- Backup low conductivity alarm limit
- Conductivity stability
• Air detector test
- Backup air detect alarm
- Primary air detect alarm (Tested if a liquid filled line is in the air detector.)
- Simulated bubble
• Conductivity verify test
- Operator prompt appearing in the instruction window: IS CONDUCTIVITY CORRECT?
- Sets primary conductivity alarm limits ±5% of displayed value

Mode	Machine status window displays	Machine action

Mode

Machine status window displays

Machine action

---

prime | PRIME |

- **Luer test**
  - Operator prompt appearing in the instruction window: **ARE PRESSURE LUERS VENTED?**

- The main alarm lamp flashes at a slow rate.
- The blood pump will operate.
- The line clamp is open.
- The self test has been successfully completed.
- The extracorporeal alarms may be disarmed for 5 minutes.
- The UF rate may be manually set from 0 to 0.5 L/h.

When the extracorporeal alarms are armed:

- The arterial pressure alarm limit set to ±50 mmHg around the indicated arterial pressure when the **PRIME** button was pressed or 10 seconds after the blood pump is turned on, off or rate changed.
- The venous pressure alarm limit is ±50 mmHg around the indicated venous pressure when the **PRIME** button was pressed or 10 seconds after the blood pump is turned on, off or rate changed.
- The TMP alarm limits set to ±35 mmHg (within the range –80 to +500 mmHg) around the indicated pressure, approximately 1 minute after the blood pump is turned on, the blood pump rate is changed or the UF rate is changed.
- The minimum low venous pressure alarm limit is approximately +10 mmHg.
- The air and blood leak detector machine alarm responses are active.

When the extracorporeal alarms are disarmed:

- The arterial pressure alarm limits are –400 and +600 mmHg.
- The venous pressure alarm limits are ±200 mmHg around the indicated venous pressure when the **ARMED / DISARM** button is pressed or 10 seconds after the blood pump starts, blood pump power switch is turned off or the blood pump rate is changed.
- The TMP alarm limits are ±200 mmHg (within the range –80 to +500 mmHg) around the indicated TMP approximately 1 minute after the UF rate is changed or the blood pump is turned on, off or rate changed.
- The air and blood leak detector machine alarm responses are disabled (except for the visual indicator).

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dialyze | DIALYZE |

- All alarms are functional. No alarm condition exists.
- The blood pump will operate.
- The line clamp is open.
- The UF rate is at the calculated value (from the **PRESCRIBED TIME** and **TARGET UF**), unless manually overridden.
- The heparin pump will operate.
- The elapsed time is accumulated.

Preliminary Draft

Mode	Machine status window displays	Machine action

Machine action

- While the blood pump is stopped and/or the machine is in bypass the elapsed time is not accumulated.

- The main alarm lamp is off.

- The accumulated ultrafiltrate removed is displayed.

- The TMP alarm limits are spread to ±200 mmHg around the indicated TMP for approximately 1 minute when the blood pump or the UF rate is changed. The maximum high TMP alarm limit is +500 mmHg. The minimum low TMP is –80 mmHg (may be technician set closer to zero).

- The TMP alarm limits set to ±35 mmHg (within the range –80 to +500 mmHg) around the indicated pressure, approximately 1 minute after the blood pump is turned on, the blood pump rate is changed or the UF rate is changed.

- The SET LIMITS button may be used to manually set the TMP, arterial pressure, venous pressure alarm limit windows.

- The arterial pressure alarm limits spread to –400 and +600 mmHg, for approximately 10 seconds, when the blood pump is started or rate is changed.

- The venous pressure alarm limits spread to ±200 mmHg around the indicated venous pressure, for approximately 10 seconds, when the blood pump is started or rate is changed.

- The arterial and venous pressure alarm limits set to ±50 mmHg of the indicated value approximately 10 seconds after the blood pump is started or rate is changed.

- The minimum low venous pressure alarm limit is approximately +10 mmHg.

Machine status window displays

ALARM

- An alarm indicator flashes to indicate the monitor that is in alarm.

- The main alarm lamp flashes.

- Audio alarm sounds.

Refer to the Alarm section of this manual for additional information.

Mode

alarm

Preliminary Draft

Glossary

Terms

These terms are defined as they apply to hemodialysis and the System 1000. The definitions are not intended to be comprehensive.

Air embolus

An air bubble (bolus or foam) carried by the bloodstream to a vessel small enough to be blocked by the bubble.

Arterial

The portion of the extracorporeal circuit which carries blood from the patient to the dialyzer.

Arterial pressure

Referring to the extracorporeal circuit, the pressure in the arterial drip chamber. The drip chamber may be between the access and the blood pump, thus measuring the pull or suction created by the blood pump, or between the blood pump and the dialyzer, measuring the pressure in the blood line as it enters the dialyzer.

Blood pump

A mechanical device for propelling blood through an extracorporeal circuit, usually by means of rollers compressing special tubing and pushing blood through tubing (peristaltic action).

Button

An area of the touch panel used by the operator to control machine operation.

Concentrate

The concentrated solution of salts which, when diluted with precise amounts of water, forms dialysate.

Conductivity

The ease with which an electric current is carried or conducted; used as a measure of dialysate salt composition.

Conductivity meter

An electronic measuring device which indicates the relative amount of conductive material in solution.

Delivery system

An electro-mechanical device which prepares dialyzing fluid (solution), monitors its preparation, and monitors various parameters of the dialysis treatment.

Dialysate

The dialyzing solution produced by the delivery system by combining precise amounts of water and chemicals. The solution typically includes physiological quantities of sodium chloride,

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potassium chloride, calcium chloride, magnesium chloride, sodium acetate and/ r sodium bicarbonate.

Dialysate pressure

The positive or negative pressure exerted on the membrane in the dialysate compartment of the dialyzer.

Dialyzer

The "artificial kidney" through which blood and dialysate flow, separated by a semi-permeable membrane, allowing dialysis and ultrafiltration to take place.

Disinfectant

A chemical that destroys most micro-organisms.

Drip chamber

An enlarged portion of the blood tubing where air is trapped and pressure can be monitored.

Effluent

The outflow from something (usually liquid); in this application dialyzing fluid that has been "used." It contains solutes not originally present.

Extracorporeal

Outside the body; generally refers to blood being circulated outside the body.

Flowmeter

A device for indicating rate of flow of liquid past a given point.

Gram

The basic unit of weight in the metric system; the weight of one cubic centimeter of water at 4°C.

1000 g = 1 kg; 454 g = 1 lb; 28.4 g = 1 oz

Hemodialysis

The process of removing accumulated metabolic waste products from the blood and restoring water-electrolyte and acid/base balance by circulating blood through an artificial kidney.

Heparin

A chemical that slows the natural clotting of blood.

Heparin pump

An electro-mechanical device used to infuse heparin into the extracorporeal circuit.

High-flux dialyzer

A dialyzer having an in-vivo UF coefficient generally greater than 8 ml/h/mmHg.

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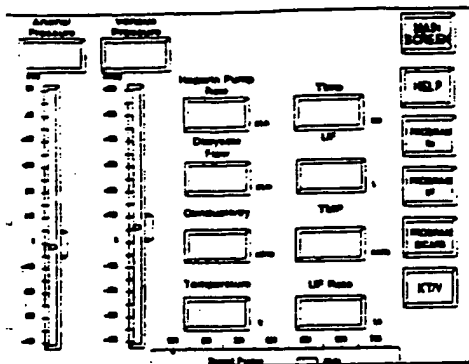
Program Screen

Rinse Screen

Normal operating range

A function is in the "normal operating range" when its value is between the low and high alarm limits.

Pascal

A unit of pressure.

$1 \text{ Pa} = 1 \text{ N/m}^2 = 0.0075 \text{ mmHg}$

Pound per square inch

A unit of pressure.

$1 \text{ psi} = 0.07 \text{ bar} = 51.7 \text{ mmHg}$

Program screen

The video screen display that contains the specialized operator controls used to select machine programable functions including programable sodium, programable UF control, and probramable bicarb. The program screen is displayed after the MENUS then PROGRAM buttons are touched.

Proportioning pump

A mechanical device which measures precise amounts of water and concentrate.

Renal

Pertaining to the kidneys; from the Latin "renis."

Rinse screen

The video screen display that contains the standard operator controls for the rinse mode options, including the HEAT CLEAN and CHEMICAL buttons. The rinse screen is displayed after the RINSE button is touched while the dialysate connectors are on the rinse block.
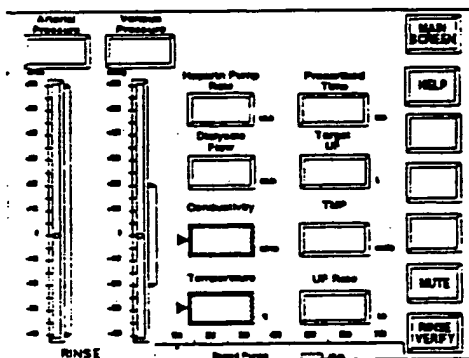
Saline

Containing salt - "saline" usually refers to an isotonic (0.9%) sodium chloride solution used to prime the dialyzer before dialysis; and to rinse blood back to the patient upon completion of dialysis; may be given during hemodialysis to prevent or correct hypotension.

Sodium hypochlorite

The active ingredient of common household bleach; used for cleaning dialysate fluid pathways of delivery systems of biological materials. It does not remove precipitates.

Standard bath

The dialysate obtained by proportioning 1 part acid concentrate to 34 parts water to 1.8 parts bicarbonate concentrate for bicarbonate dialysate or 1 part acetate concentrate to 34 parts water for acetate concentrate.

Pr liminary Draft
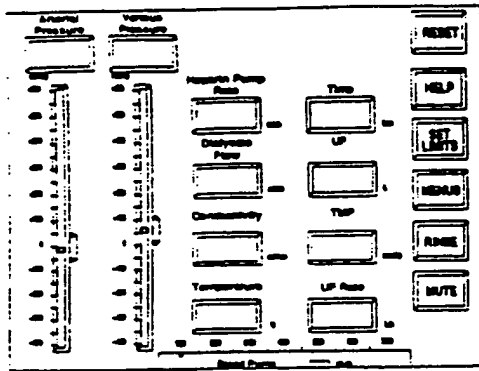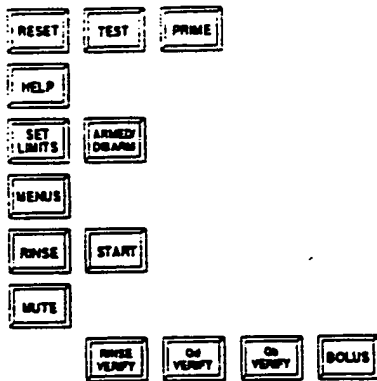
Main Screen

Main Screen Buttons
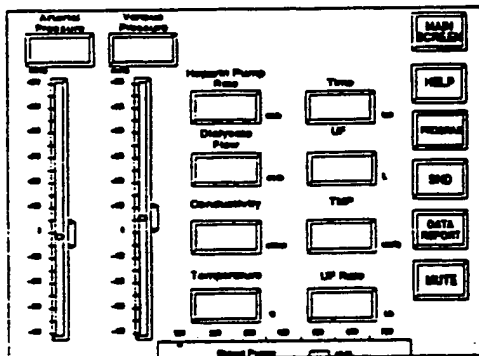
Menus Screen

Hydrophobic transducer protector

A transducer protector that does not allow liquid to pass through it.

Inch f mercury

A unit of pressure.

1 inHg = 3386.4 Pa = 25.4 mmHg = 13.6 inH_2O

Inch of water

A unit of pressure.

1 inH_2O = 249.09 Pa = 1.8 mmHg = 0.07 inHg

Kilogram

A metric unit of weight.

1 kg = 1000 g = 2.2 lb

LED

Light emitting diode; a solid-state, low-current lamp used as an indicator.

Liter

The basic unit of volume in the metric system.

1 L = 1000 ml = 1.057 qt (US)

Main screen

The video screen display that contains the standard operator controls including button #1 as RESET, PRIME or TEST. The main screen is the standard or default operator's screen.

Menus screen

The video screen display that contains the specialized operator controls including the PROGRAM, SND and DATA REPORT buttons. The menus screen is displayed after the MENUS button is touched.

Milliliter

A metric unit of volume.

1 ml = 0.001 L = 1 cc

Millimeters of mercury

A metric measure of pressure or vacuum.

1 mmHg = 133.32 Pa = 0.02 psi

Millisiemens per centimeter

A metric unit of conductivity measurement same as millimho per centimeter.

Negative pressure

Pressure which is below atmospheric or "minus" (suction).

Standard dialysate

Standard bath

Sterile

Completely free of any living microorganisms.

Thermistor

A temperature sensing device used in electrical temperature control circuits. A small sensitive metal device that changes its electric characteristics with temperature change.

Transmembrane pressure

The hydrostatic pressure difference inside the dialyzer across the membrane from the blood side to the dialysate side.

$$TMP = \frac{B_i + B_o}{2} - \frac{D_i + D_o}{2}$$

where:

B_i = blood pressure in

B_o = blood pressure out

D_i = dialysate pressure in

D_o = dialysate pressure out

The usual approximation of $B_o - D_i$ is used to determine the TMP that is displayed on the System 1000 screen.

Ultrafiltration

The process by which water (with electrolytes) moves across the dialyzer membrane as a net result of transmembrane and osmotic pressure differences between the blood and the dialysate. For a given osmotic pressure, the greater the transmembrane pressure the more rapid the ultrafiltration.

Ultrafiltration coefficient (KUF)

The amount of liquid that passes through the dialyzer is given by ml/h/mmHg.

Ultrasonic

High frequency sound waves that are above the normal hearing range. Such sound waves are often used to detect air bubbles in the venous line.

Venous

The portion of the extracorporeal circuit which carries blood from the dialyzer to the patient.

Video screen

Th CRT (screen) that displays machine functions and controls.

Window

> An area of the video screen that displays the value of monitored functions.

Preliminary Draft

Symbols and Abbreviations

A	ampere
AAMI	Association for the Advancement of Medical Instrumentation
ac	alternating current
Btu	British thermal unit
cc	cubic centimeter
CC	direct current (*international symbol*)
cm	centimeter
dc	direct current
ft	foot
g	gram
gal/min	gallon per minute
h	hour
Hb/L	hemoglobin per liter
Hz	hertz
ID	inside diameter
in	inch
inHg	inch of mercury
inH$_2$O	inch of water
kg	kilogram
kPa	kilopascal
KUF	coefficient of ultrafiltration
L	liter
L/h	liter per hour
lb	pound
m	meter
mA	milliampere
mEq/L	milliequivalent per liter
mg	milligram
min	minute
ml	milliliter
ml/h	milliliter per hour
ml/min	milliliter per minute
mm	millimeter
mmHg	millimeter of mercury
mS/cm	millisiemens per centimeter
oz	ounce
Pa	pascal
psig	pound per square inch, gauge

qt	quart
s	second
μA	microampere
μL	microliter
V	volt
W	watt
°C	degree Celsius
°F	degree Fahrenheit
<	less than
>	greater than

Reference

This section describes in detail the use and operation video screen touch panel controls.

Arterial Pressure -14 mmHg

Venous Pressure +54 mmHg

Heparin Pump Rate 5.0 mL/h

Elasped Time :30 h.m

Dialysate Flow 500 mL/m

UF Removed .75 L

Conductivity 14.20 mS/cm

TMP 55 mmHg

Temperature 38.0 °C

UF Rate 1.50 L/h

RESET

HELP

SET LIMITS

MENUS

RINSE

MUTE

DIALYZE

Blood Pump
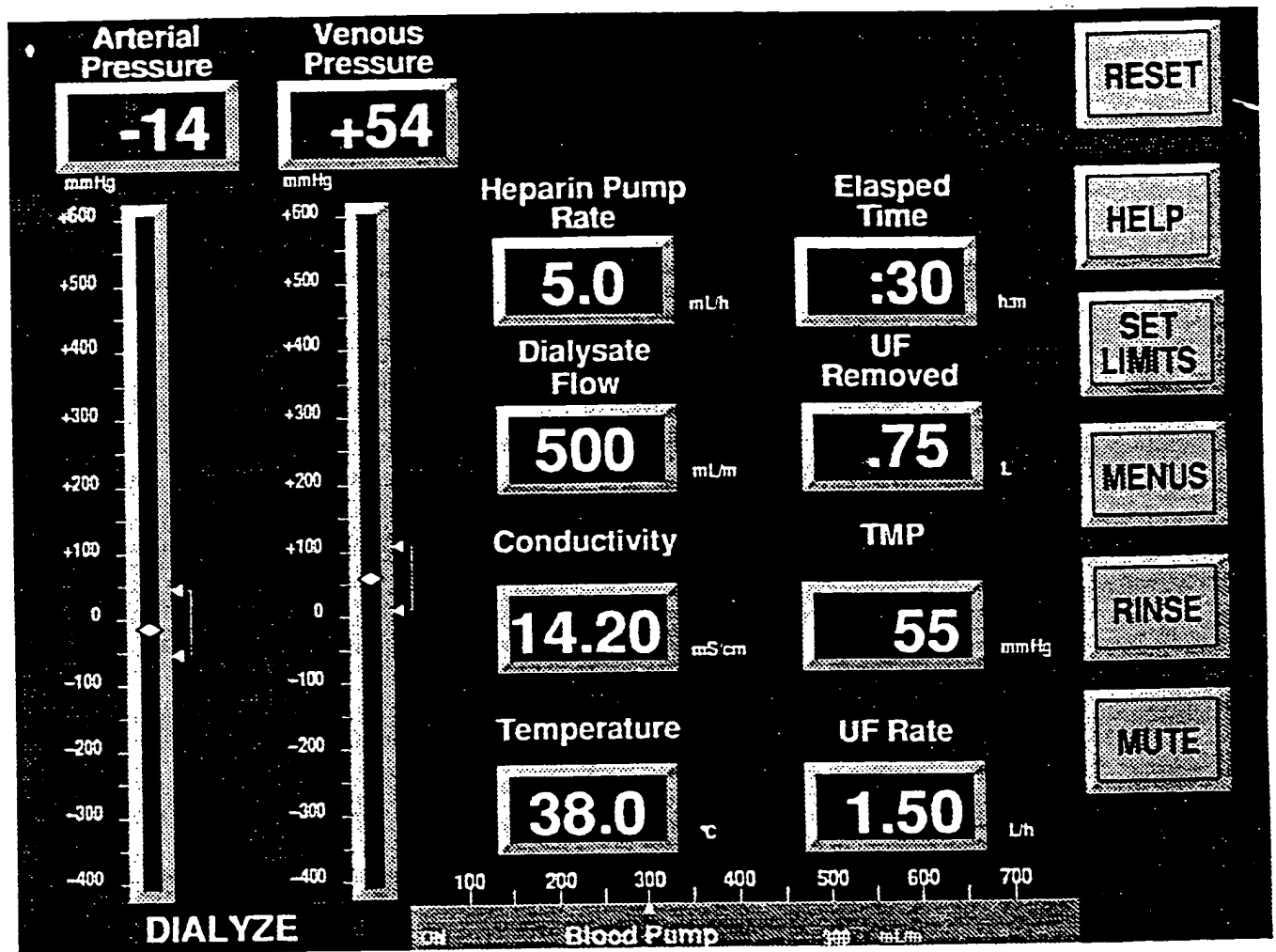
Monitor windows

VENOUS PRESSURE window

Displays the pressure in the venous drip chamber.

ARTERIAL PRESSURE window

Displays the pressure in the arterial drip chamber.

HEPARIN PUMP window

Displays the heparin pump infusion rate.

When the heparin pump is off, OFF is displayed above the window.

DIALYSATE FLOW window

Displays the dialysate flow rate. When the machine is in bypass, BYPASS is flashed above the window.

CONDUCTIVITY window

Displays the conductivity of the dialysate.

Displays the conductivity alarm limits when the CONDUCTIVITY window is pressed.

The window reverts to display the actual conductivity after approximately 10 seconds.

TEMPERATURE window

Displays the temperature of the dialysate.

Displays the minimum and maximum settable temperature when the TEMPERATURE window is pressed.

PRESCRIBED TIME window

Displays the operator adjusted dialysis treatment time in hours and minutes.

Changes to the ELAPSED TIME window when dialysis is started.

TARGET UF window

Displays the operator adjusted desired fluid loss in liters.

Changes to the UF REMOVED window when dialysis is started.

TMP window

Displays the transmembrane pressure as calculated by the blood pressure out minus the dialysate pressure in.

Displays the TMP alarm limits when the TMP window is touched. The TMP alarm limits are active while the machine is in the Dialyze Mode. Approximately one minute after the UF rate is set, the TMP alarm limits close to ±35 mmHg around the actual TMP at that time. If the UF rate is changed, the blood pump stops, starts or blood pump rate changes; the TMP alarm limits open for approximately one minute then close to ±35 mmHg around the actual TMP at that time. The alarm limits may be set manually by pressing the SET LIMITS button.

Preliminary Draft

PRIME

Arterial Pressure	Venous Pressure
-1 mmHg	15 mmHg

Heparin Pump Rate
5.0 mL/h

Dialysate Flow
500 mL/m

Conductivity
14.20 mS/cm

Temperature
38.0 ℃

Prescribed Time
4:00 h:m

Target UF
6.00 L

TMP
55 mmHg

UF Rate
1.50 L/h

Blood Pump mL/m

RESET

HELP

ARMED/ DISARM

MENUS

RINSE

MUTE
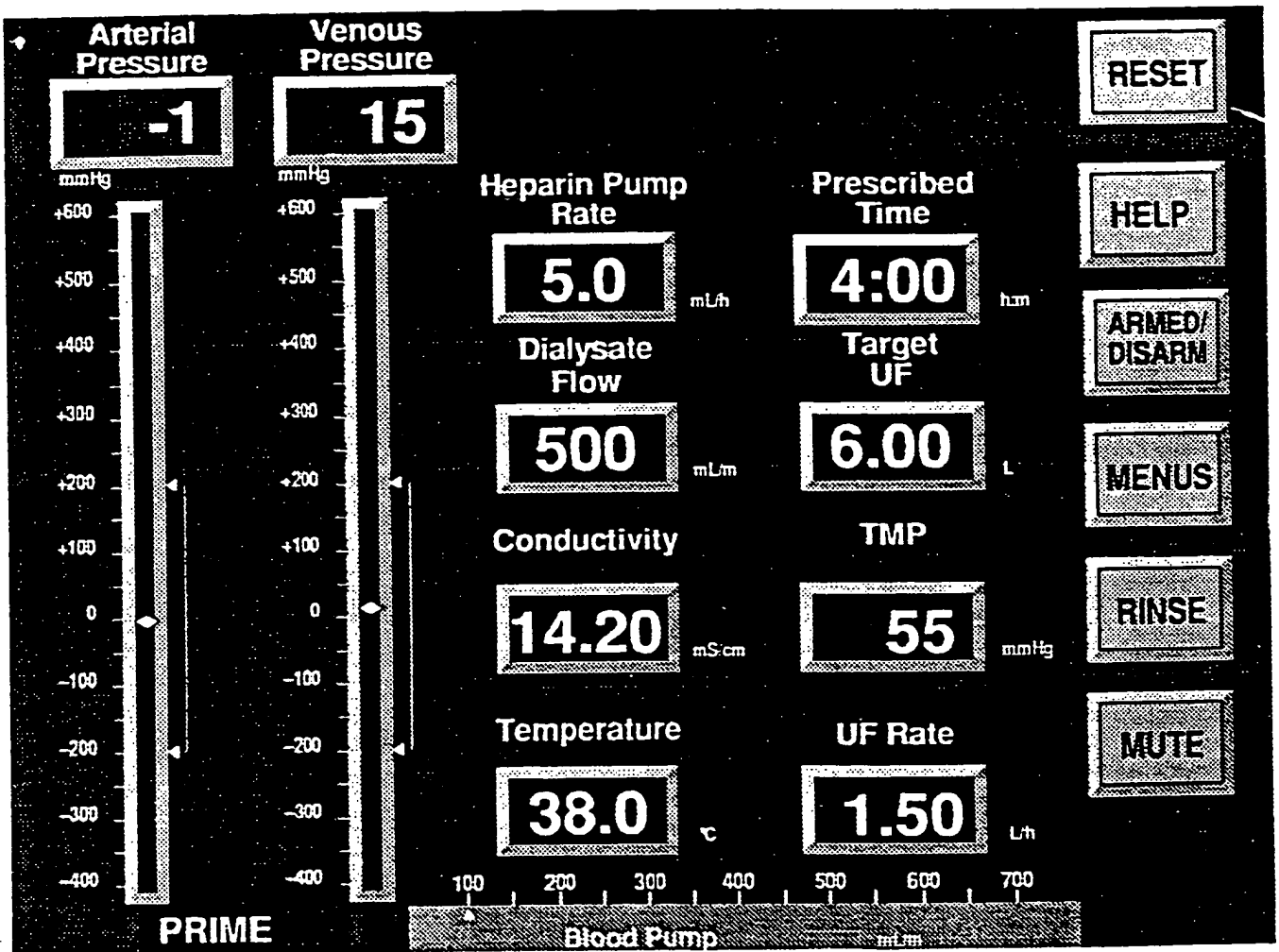
ELAPSED TIME window

> Displays the actual elapsed time after the START button has been touched while the blood pump turned (i.e., periods of time in which the blood pump does not turn are not counted in the displayed value).

> Displays the prescribed dialysis time when the window is touched after dialysis has started.

UF REMOVED window

> Displays the actual ultrafiltrate removed after the START button has been touched.

> Displays the operator adjusted target fluid loss when the window is touched after dialysis has started.

UF RATE window

> Displays the ultrafiltration rate.

> The ultrafiltration rate may be set in one of two method; i.e., manually by entering the operator calculated ultrafiltration rate or indirectly by entering the prescribed dialysis time and target fluid loss with the machine calculating the ultrafiltration rate. When the operator manually enters the ultrafiltration rate MANUAL is displayed above the UF RATE window. When the machine calculates the ultrafiltration rate from the operator inputted dialysis time and target fluid loss, then CALCULATED is displayed above the UF RATE window.

Buttons

The appearance function of the buttons change as required during operation.

RESET button (button #1)

> Resets extracorporeal alarm conditions when the alarm situation is corrected.

TEST button (button #1)

> Appears, in the rinse mode, when the conductivity and temperature reach the normal operating range. Initiates the Self Test Mode.

PRIME button (button #1)

> Appears after the satisfactory completion of the Self Test Mode. Initiates the Prime Mode.

MAIN SCREEN button (button #1)

> Appears when the MENUS, PROGRAM or RINSE button is touched (menus, program or rinse screen respectively). Returns the display to the main screen.

SET LIMITS button (button #3)

> Sets the arterial pressure, venous pressure and TMP alarm limits in the dialyze mode. The limits will set immediately.

Arterial Pressure -14 mmHg

Venous Pressure +54 mmHg

Heparin Pump Rate 5.0 mL/h

Elasped Time :30 h:m

Dialysate Flow 500 mL/m

UF Removed .75 L

Conductivity 14.20 mS/cm

TMP 55 mmHg

Temperature 38.0 ℃

UF Rate 1.50 L/h

DIALYZE

Blood Pump 100 200 300 400 500 600 700 mL/m

RESET
HELP
SET LIMITS
MENUS
RINSE
MUTE
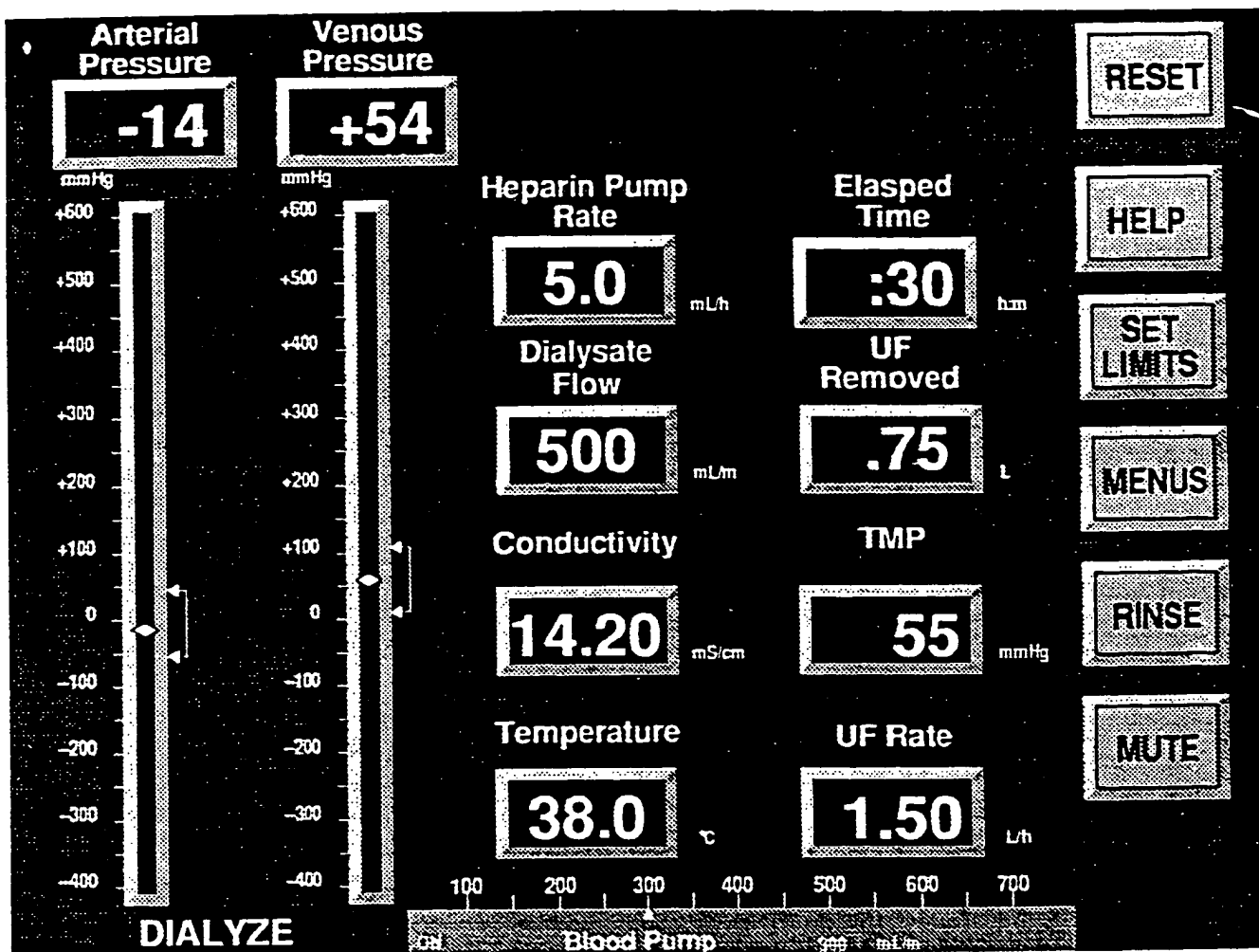
ARMED/DISARM button (button #3)

Disarms the air and blood leak detector alarms and sets the opens the arterial (−400 to +600 mmHg) and venous (±200 mmHg) alarm limits windows during the Prime Mode. The disarm period lasts approximately 5 minutes while the blood pump is on.

While the alarms are disarmed, the ARMED/ DISARM button displays ARMED/ DISARM in dark letters on a light field (reverse). The extracorporeal alarms may be manually rearmed by touching the button while it is displayed in reverse.

After the disarmed period the air and blood leak detector alarms become active and the arterial and venous pressure alarm limits close to ±50 mmHg around the respective indicated pressure.

PROGRAM button (button #3)

Appears when the MENUS button is touched (menus screen). This button will be used for future machine functions.

MENUS button (button #4)

Displays the menus screen with additional control options such as data report and future machine functions.

SND button (button #4)

Appears when the MENUS button is touched (menus screen). This button will be used for future machine functions.

RINSE button (button #5)

Initiates the Rinse Mode when the rinse interlocks are met.

START button (button #5)

Starts the Dialyze Mode.

DATA REPORT button (button #5)

Appears when the MENUS button is touched (menus screen). Displays the data report containing treatment information such as prescribed treatment time, elapsed treatment time, target UF, UF removed, UF remaining, total blood processed and total heparin infused.

MUTE button (button #6)

Silences most audio alarms for approximately 100 seconds.

Q_b VERIFY button (button #7) (Button #7 appears when required.)

Appears when the blood pump display is touched. Sets the blood pump speed to the value indicated in the display. If the Q_b VERIFY button is not touched within approximately − second after the blood pump display was changed, the button will disappear and the blood pump rate will continue at its previous setting.

```
 _____
|            |
|    Qb      |
|  VERIFY    |
|_____|
```
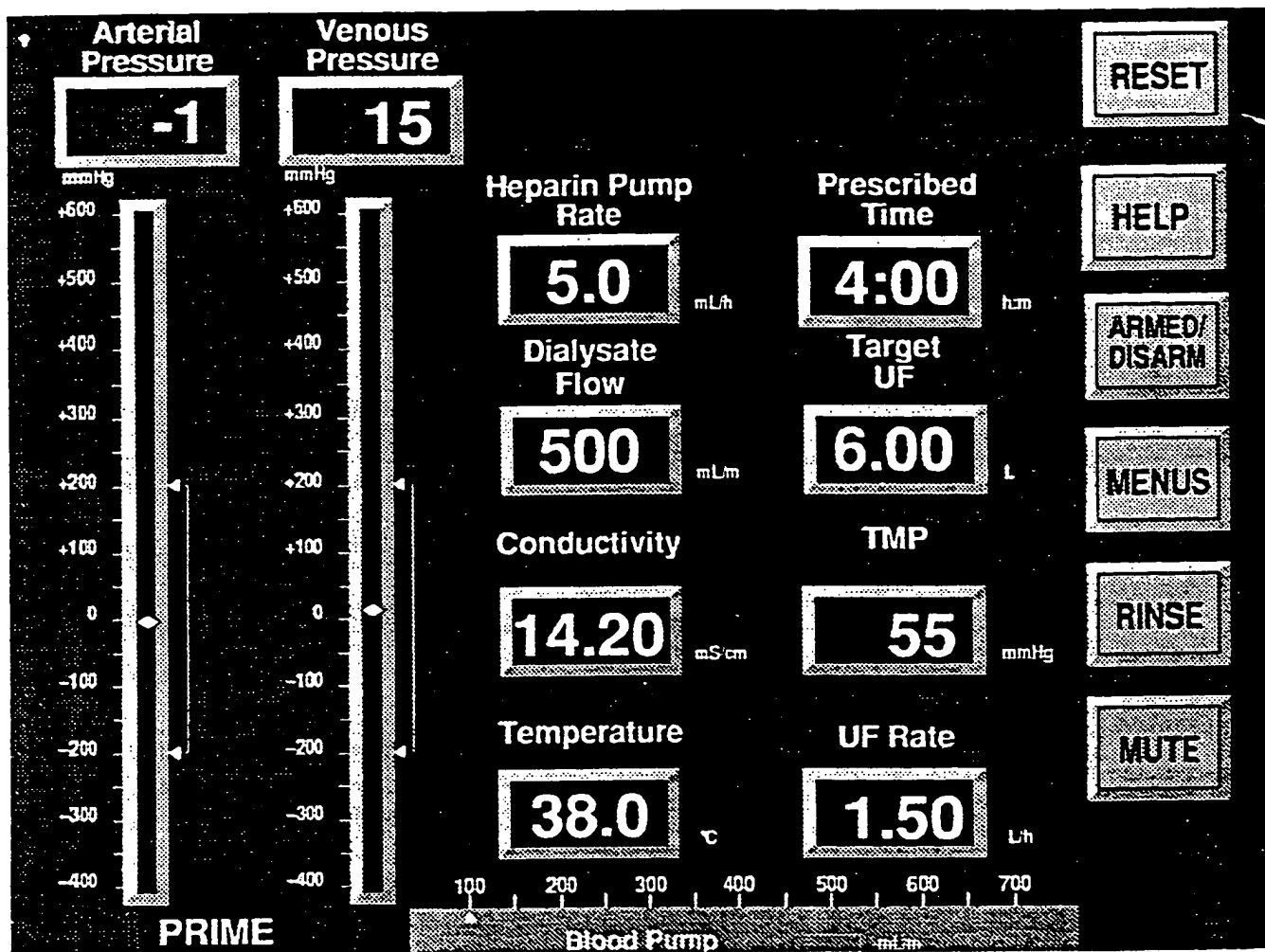
Qd VERIFY

Q_d VERIFY button (button #7) (Button #7 appears when required.)

Appears when the DIALYSATE window is touched. Sets the dialysate flow rate to the value displayed in the window. If the Q_d VERIFY button is not touched within approximately 3 second after the window was pressed, the button will disappear and the dialysate flow rate will continue at its previous setting.

RINSE VERIFY

RINSE VERIFY button (button #7) (Button #7 appears when required.)

Appears when the RINSE button is touched and the dialysate lines are on the rinse block. Starts the rinse mode. If the RINSE VERIFY button is not touched within approximately 3 second after the RINSE button was pressed, the verify button will disappear and the machine will continue at its previous mode.
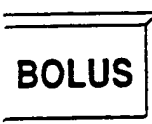
BOLUS

BOLUS button (button #7) (Button #7 appears when required.)

Appears when the HEPARIN PUMP window is touched. Delivers a bolus of heparin. If the BOLUS button is not touched within approximately 3 second after the window was pressed, the button will disappear. The bolus size is set by the service technician, either 0.5 or 1 ml.

Blood pump display

Displays the blood pump setting in milliliters per minute in 10 ml/min increments on an analog scale and in a digital display. The touch sensitive analog scale is used to input the desired blood pump setting.

When the blood pump is off, OFF is displayed in the blood pump display.

When the blood pump is on, ON is displayed in the blood pump display.

Arterial and venous pressure displays and alarm limit indicators

In order to prevent nuisance alarms, the arterial or venous pressure alarm limit must be violated for more than 5 seconds to cause an arterial or venous pressure alarm.

During the Dialyze Mode with the blood pump power switch turned on, the low venous pressure alarm limit will not go below +10 mmHg.

During the rinse mode, the arterial pressure alarm limits are wide open; i.e., -400 to +600 mmHg. The venous pressure alarm limits are set ±200 mmHg around the indicated venous pressure at the beginning of the Rinse Mode.

When the blood pump is started or turned off, or the rate changed, the arterial pressure alarm limits open to -400 to +600 mmHg, the venous alarm limits open to ±200 mmHg around the appropriate indicated pressure. After 10 seconds the alarm limits close to ±50 mmHg around the respective indicated pressure.

The arterial and venous alarm limits may be manually set to ±50 mmHg of the indicated pressures by touching the SET LIMITS button.

Arterial pressure display and alarm limit indicator

Venous pressure display and alarm limit indicator

Arterial Pressure -14 mmHg	**Venous Pressure** +54 mmHg	

Heparin Pump Rate 5.0 mL/h

Elasped Time :30 h:m

Dialysate Flow 500 mL/m

UF Removed .75 L

Conductivity 14.20 mS/cm

TMP 55 mmHg

Temperature 38.0 °C

UF Rate 1.50 L/h

RESET

HELP

SET LIMITS

MENUS

RINSE

MUTE

Qb VERIFY

DIALYZE

Blood Pump

100 200 300 400 500 600 700

Blood pump display

Preliminary Draft

Reference 9

Preliminary Draft
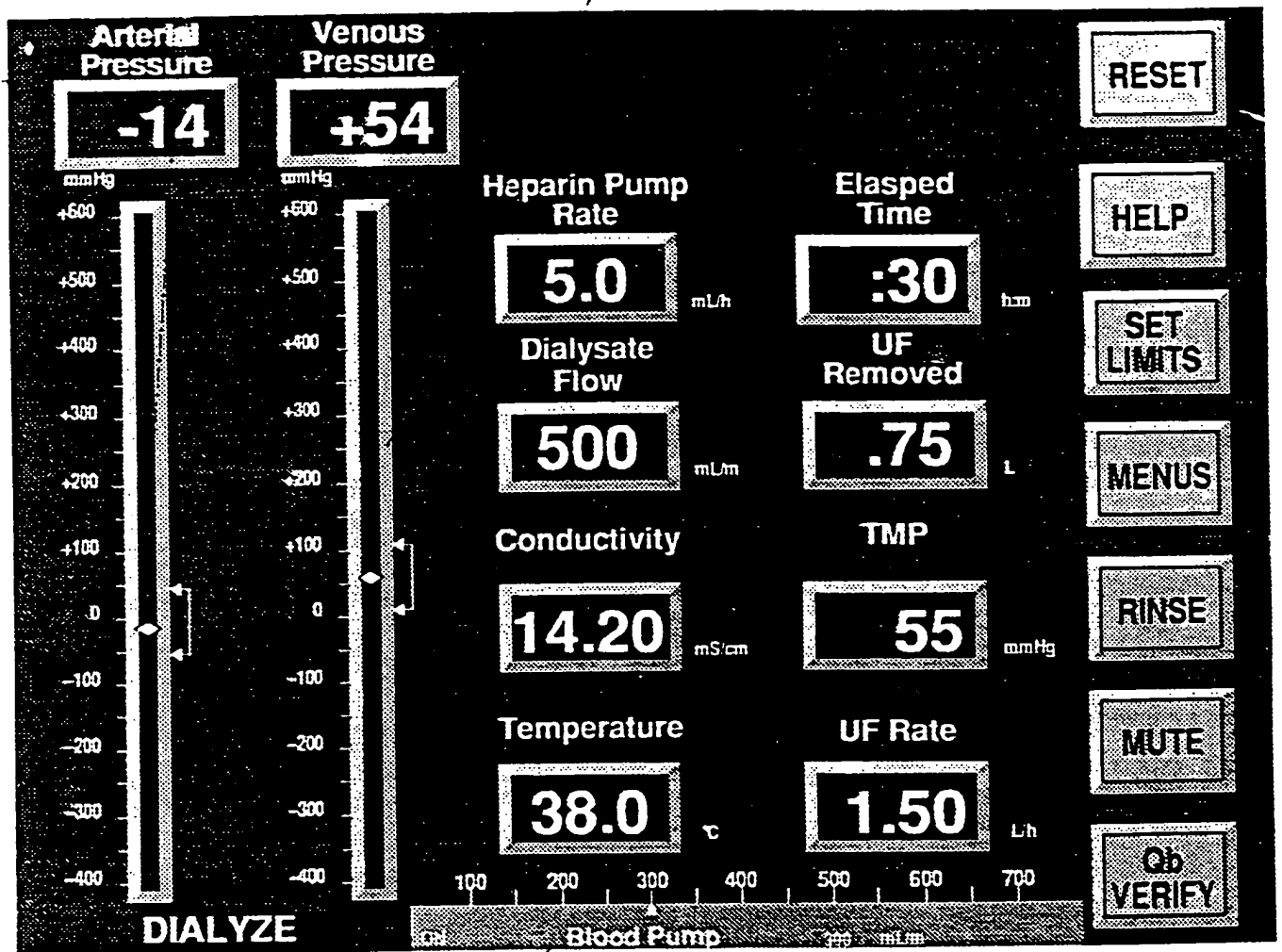
Problem Solving

The following is a list of some operator-correctable problems. If a machine problem occurs, first check this list. If the problem still cannot be corrected, contact a qualified service technician.

WARNING:
Problem solving and repair of this machine should be perform d by trained and authorized personnel only. If your center does not hav technical personnel trained in the repair of this machine, service may be obtained through Althin CD Medical, Inc. Contact your Field Service Representative.

Patient

Respond to a Hypotensive Episode

Note:

The following procedure should be followed when the operator wishes to quickly minimize the ultrafiltration rate during dialysis.

1. Press the UF RATE window.

2. Use the calculator keypad to input the desired UF rate in liters per hour.

3. Press the calculator ENT button to enter the UF rate as displayed in the calculator window.

4. Treat the patient for hypotension.

   Use a procedure recommended by the attending physician.

5. When indicated, resume dialysis or terminate treatment.

   Follow the attending physician's directives.

   To return to the calculated UF rate:

   a. Press the UF REMOVED window. The previously set desired fluid loss is displayed in the calculator window.

   b. Press the calculator ENT button to re-enter this desired fluid loss.

   To change the desired fluid loss:

   a. Press the UF REMOVED window.

   b. Use the calculator keypad to input the new desired fluid loss in liters.

   c. Press the calculator ENT button to enter the fluid loss as displayed in the calculator window.

Blood Pump

Blood pump will not turn

1. Blood pump door is not fully closed.

   Fully close the blood pump door.

2. Foreign object jammed in the blood pump.

   a. Turn ff the blood pump.

   b. Remove the foreign object.

   c. Turn on the blood pump flow.

    d. If it still will not turn, discontinue dialysis according to your center's procedure.

3. OVERSPEED alarm

    a. Turn off the blood pump.

    b. Wait 5 seconds.

    c. Turn on the blood pump.

    d. If you get another overspeed alarm, discontinue dialysis according to your center's procedure.

4. OVERSPEED alarm during the Self Test Mode.

    a. Turn off the blood pump. Do not manually turn on the blood pump during the Self Test Mode.

Self Test

Self Test failed

Note: **If the TMP did not pass Self Test, check for air in the fluid path. Remove the air as required. Then repeat Self Test.**

1. Start Self Test again.

    a. Make sure the pressure luers are properly plugged and the conductivity is checked with an independent test against a known standard.

    b. Repeat self test.

    c. If the test fails again, have the machine service by a qualified service technician.

Pulse spot

The pulse spot is not flashing

1. Internal machine failure.

    a. Discontinue dialysis according to your center's procedure.

    b. Have the machine service by a qualified service technician.

Air Detector

Air detector alarm

1. Check for air in the blood line.

If there is no air, make sure the line is properly positioned in the air detector.

2. Worn air detector bumper.

Refer replacement of the bumper to a qualified service technician.

Blood Leak Detector

Blood leak alarm

1. Leak in the dialyzer membrane.

    a. Check for the presence of blood in the "from dialyzer" dialysate line.

    b. If no blood is visible, obtain a sample of used dialysate from the sample port.

Preliminary Draft

    c.   Verify the presence of blood in the used dialysate, using your center's procedure.

    d.   Use your center's procedure for the correct action to tak   when a minor or major blood leak occurs.

3. **The blood detector is dirty.**

Have a qualified service technician clean the blood detector.

4. **The blood detector LED is burned out.**

Have the machine repaired by a qualified service technician.

Air in Dialysate Circuit

Excessive air in circuit.

1. **Loose or non-sealing dialysate line connector.**

Securely attach the connector to the dialyzer. If air is still present, discontinue dialysis.

2. **Dialyzer UF coefficient too low for the desired UF rate.**

    a.   Reduce the UF rate.

    b.   Use a dialyzer with an appropriate (larger) UF index.

3. **Have a qualified service technician check for a loose fitting.**

    a.   Inspect the hydraulic circuit for location where air is being drawn in.

    b.   Tighten loose fitting.

Ultrafiltration

Weight removed from patient not as expected.

1. **Erroneous accounting of patient predialysis weight, food and fluid intake and output during dialysis treatment.**

Recalculate the weight to be removed. Closely monitor eating, drinking and elimination during treatment. Be sure to account for priming and rinseback if applicable. Refer to the "UF Control Worksheet" in the Appendix of this manual.

Rinse

Machine will not go into rinse.

WARNING
Make sure that the patient is disconnected from the dialyzer and bl   d lines before starting the rinse mode.

1. **The dialysate lines are not on the rinse block.**

Make sure the dialysate connectors are securely connected to the rinse block.

2. **The RINSE VERIFY button was not pressed.**

Make sure the RINSE VERIFY button is pressed within approximately 5 seconds after the RINSE button is pressed.

Conductivity

Conductivity alarm

1. **Concentrate container is empty.**

   Refill the concentrate container.

2. **Open end of concentrate line is not at the bottom of the container.**

   Place the end of the concentrate line at the bottom of the container.

3. **Undissolved bicarbonate salts have settled to the bottom of the container.**

   Gently shake or rock the container to mix the solution.

4. **Concentrate lines in the wrong machine fittings or containers.**

   Reconnect the concentrate lines to the correct machine fittings and/or containers.

   Make sure the correct concentrate is in the container.

   For acetate dialysis:

   Make sure that acid/acetate concentrate line is connected to a container of acetate concentrate.

   Make sure the bicarbonate concentrate line is connected to the bicarbonate rinse fitting.

   For bicarbonate dialysis:

   Make sure that acid/acetate concentrate line is connected to a container of acid concentrate.

   Make sure the bicarbonate concentrate line is connected to a container of bicarbonate concentrate.

Dialysate conductivity not as expected.

1. **Using the wrong concentrate(s).**

   Check the manufacturer's labels on the concentrate containers to make sure that the correct concentrate(s) is being used.

2. **Impure water (conductivity higher than expected).**

   Confirm the purity of the water and proper functioning of the water pretreatment equipment.

3. **Wrong concentrate formulation or combination being used.**

   Check the manufacturer's labels on the concentrate containers to make sure that the concentrate(s) being used will yield the correct dialysate ionic profile as prescribed.

4. **Proportioning error.**

   Call service.

5. **Bicarbonate precipitate**

   Rinse fluid path with vinegar

Preliminary Draft

Power off alarm

1. **Power cord is unplugged.**

   Plug in the power cord.

2. **The wall outlet has stopped providing power.**

   Discontinue dialysis according to your center's "power-loss" procedure.

WARNING:
Be sure to remove the venous blood line from the line clamp before discontinuing dialysis during a power fall alarm.

Preliminary Draft

Special Operations

This section provides detailed instructions on the specialized functions of the System 1000 machine.

Control Ultrafiltration

The System 1000 automatically calculates and maintains the ultrafiltration removal rate from the prescribed treatment time and the total ultrafiltrate to be removed.

The operator enters the prescribed treatment time in the PRESCRIBED TIME window and the desired fluid to be removed in the TARGET UF window. The machine automatically calculates the UF rate. The desired volume of fluid is removed from the patient's blood. The total volume of fluid removed (in liters) is displayed continuously in the UF REMOVED window.

To set the prescribed dialysis time:

a. Touch the PRESCRIBED TIME window.

b. Use the keypad to input the prescribed dialysis time in hours and minutes.

c. Touch the keypad ENT button to enter the prescribed dialysis time as displayed in the keypad window.

To change the prescribed dialysis time after dialysis has started:

a. Touch the ELAPSED TIME window.

b. Use the keypad to input the prescribed dialysis time in hours and minutes.

c. Touch the keypad ENT button to enter the prescribed dialysis time as displayed in the keypad window.

    If the previously set treatment time is to be restored, touch the RST then the ENT buttons.

To set the desired fluid loss:

a. Touch the TARGET UF window.

b. Use the keypad to input the desired fluid loss in liters.

c. Touch the keypad ENT button to enter the fluid loss as displayed in the keypad window.

To change the desired fluid loss after dialysis has started:

a. Touch the UF REMOVED window.

b. Use the keypad to input the new desired fluid loss in liters.

c. Touch the keypad ENT button to enter the fluid loss as displayed in the keypad window.

    If the previously set desired fluid loss is to be restored, touch the RST then ENT buttons.

To set a manual UF rate (as in response to a hypotensive episode):

    a. Touch the UF RATE window.

    b. Use the keypad to input the desired UF rate in liters per hour.

    c. Touch the keypad ENT button to enter the UF rate as displayed in the keypad window.

To return to the calculated UF rate from a manual UF rate after dialysis has started:

    a. Touch the UF REMOVED window. The previously set desired fluid loss is displayed in the keypad window.

    b. Touch the keypad ENT button to re-enter this desired fluid loss.

    Automatically the UF rate will change to the calculated value.

To continue removing a minimal amount of fluid from a patient after the target UF has been reached (Operator can not get to the patient for a few minutes to discontinue dialysis.):

    a. Touch the UF REMOVED window.

    b. Determine the new desired target fluid loss.

    New target UF = target UF that has already been removed + maximum amount of additional fluid to be removed from the patient

    c. Use the keypad to input the new target UF.

    d. Touch the keypad ENT button to enter the fluid loss as displayed in the keypad window.

    e. *Immediately*, set the manual minimum UF rate.

WARNING: If the manual UF rate is not set immediately, a very high calculated UF rate will be set since the prescribed treatment time has been met or only a small amount of time remains.

Heparin

To set or change the heparin pump infusion rate:

    a. Touch the HEPARIN PUMP window.

    b. Use the keypad to input the heparin pump infusion rate.

    c. Touch the keypad ENT button to enter the heparin pump infusion rate.

    If the previously set heparin pump rate is to be restored, touch the RST then ENT buttons.

To stop infusion / Turn off the heparin pump:

    a. Touch the HEPARIN PUMP window.

    b. Use the keypad to input a .0 heparin pump infusion rate.

    c. Touch the keypad ENT button.

Preliminary Draft

To infuse a heparin bolus:

Note:
The bolus size, either 0.5 or 1 ml, is set by the service technician.

a. Touch the HEPARIN PUMP display.

b. Touch the BOLUS button.

To determine the total heparin infused:

a. Touch the MENUS button.

b. Touch the DATA REPORT button.

c. Note the TOTAL INFUSED HEPARIN.

Blood Pump

To turn on the blood pump:

a. Press the blood pump power switch. The switch lamp will light.

To set a blood flow rate:

a. Touch the BLOOD PUMP display bar in the area of the desired flow rate. The blood pump speed may be set in 10 ml/min increments.

b. Move your finger sideways slightly until the desired flow rate is visible in the blood pump digital window.

c. Touch the Q_b VERIFY button.

To change blood pump speed:

a. Touch the BLOOD PUMP display bar in the area of the desired flow rate.

b. Move your finger sideways slightly until the desired flow rate is visible in the blood pump digital window.

c. Touch the Q_b VERIFY button.

To determine total blood processed:

a. Touch the MENUS button.

b. Touch the DATA REPORT button.

c. Note the TOTAL BLOOD PROCESSED.

To turn off the blood pump:

a. Press the blood pump power switch. The switch lamp will turn off.

Alarm Limits

To manually set the arterial, venous and TMP alarm limits (in dialyze).

a. Touch the SET LIMITS button. The arterial and venous alarm limits will automatically set to ±50 mmHg around the displayed

pressures. The minimum low venous alarm limit is +10 mmHg. The TMP alarm limits automatically set to ±35 mmHg around the displayed TMP. The minimum low TMP alarm limit is -80 mmHg. The maximum high TMP alarm limit is +500 mmHg.

To open and re-center the arterial or venous pressure alarm limits:

a. Touch the arterial or venous analog display bar anywhere along the display.

The alarm limits will open and re-center around the displayed value. After approximately 10 seconds the alarm limits will reset to ±50 mmHg of the displayed value.

To determine the primary conductivity alarm limits:

a. Touch the CONDUCTIVITY window.

The primary conductivity alarm limits will be displayed in the window. The primary conductivity alarm limits are set to ±5% of the displayed conductivity value when the conductivity is verified by the operator during Self Test.

To determine the TMP alarm limits:

a. Touch the TMP window.

The TMP alarm limits will be displayed in the window. During dialyze, the TMP alarm limits are set to ±35 mmHg of the displayed TMP value approximately one minute after the blood pump is turned on, the blood pump rate changed, or the UF rate changed. The minimum low TMP alarm limit is -80 mmHg. The maximum high TMP alarm limit is +500 mmHg.

To open and re-center the arterial, venous and TMP alarm limits:

a. Touch the RESET button.

The alarm limits will open and re-center around the displayed value. After approximately 10 seconds the arterial and venous alarm limits will reset to ±50 mmHg of the displayed value. The TMP alarm limits will reset to ±35 mmHg of the displayed value.

Dialysate Flow Rate

The dialysate flow rate may be set from 500 to 1000 ml/min in 100 ml increments.

To set the dialysate flow rate:

a. Touch the DIALYSATE FLOW window.

b. Touch the window repeatedly until the desired flow rate is indicated in the window.

c. When the desired flow rate is displayed press the Q_d VERIFY button.

Preliminary Draft

With Nephrex° solution:

Supplies
- Gloves resistant to the disinfectant
- Nephrex HD disinfecting solution concentrate
  - o   Trademark of Surgikos
- Nephres HD disinfecting solution effectiveness test kit
- Nephrex residual test kit

Preconditions
- The patient is disconnected from the dialyzer and blood lines.
- The machine is in rinse and has been rinsed for at least 10 minutes prior to infusing a disinfectant.
- Fresh activated Nephrex concentrate has been prepared by adding 3 ml of activator to 150 ml of concentrate. Refer to the Nephrex labeling for detailed actions.

Procedure

WARNING: Be careful when handling disinfectants. Read and follow the instructions for the safe handling of disinfectants on the warning label on the bottle.

CAUTION: Use activated Nephrex concentrate within one hour of preparation.

1. Connect the disinfect line (yellow connector) to a container f activated Nephrex concentrate.

   Refer to the disinfectant labeling for detailed instructions.

2. Connect the acid/acetate concentrate line (pink connector) to the disinfect rinse port (yellow).

3. Infuse disinfectant into the fluid path for approximately 15 minutes.

4. Test for the presence of Nephrex at the drain line.

   a. Take a sample from the drain line.

   b. Test the sample using the directions given on the Nephrex disinfecting solution effectiveness kit container.

   c. Continue infusing Nephrex solution as required.

5. Infuse unactivated Nephrex concentrate for approximately 3 minutes.

   a. Disconnect the disinfect line from the activated Nephrex supply.

   b. Connect it to a container of unactivated Nephrex concentrate (approximately 50 ml).

CAUTION: Undiluted (unproportioned) activated Nephrex may form a gel or gummy solid after prolonged storage.

6. After the needed infusion, turn off the machine.

7. Disconnect the machine from the unactivated Nephrex supply.

   To disconnect the machine:

   a. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

b. Wait approximately 15 seconds for the disinfect line to drain, th n connect the disinfect line (yellow connector) to the disinfect rinse port (yell w).

8. Label the machine with a disinfectant warning sign on which the date, time and type of disinfectant have been recorded.

9. Allow the Nephrex solution to remain in the fluid pathway for at least 15 minutes.

WARNING: **Make sure that the disinfectant remains in the fluid pathway long enough for adequate disinfection. Refer to the chemical disinfectant manufacturer's labeling for detailed information.**

10. Before the next use, rinse the fluid pathway for at least 10 minutes with water.

11. Test a dialyzer circuit sample of rinse solution for the presence of Nephrex.

   a. Withdraw a sample of the rinse solution from the dialyzer circuit.

   b. Test the sample for residual disinfectant using Nephrex residual test kit. Refer to the Nephrex labeling for detailed actions.

WARNING: **Make sure that the determination test shows a sufficiently low level of disinfectant in the rinse solution before dialysis. Refer to the attending physician's directives for the acceptable limit, the chemical disinfectant manufacturer's labeling and the AAMI standard for hemodialysis.**

To ensure that the disinfectant level in the dialyzer circuit is below a level acceptable for patient safety, sample the rinse solution in the dialysate lines.

Make sure that the determination test is specific for the disinfectant used.

Clean and disinfect machine external surfaces

Supplies
- Mild detergent solution, such as a mild dishwashing liquid in water
- Diluted bleach solution [4 part household bleach (5.25% sodium hypochlorite) and 126 parts cold water], for example, 40 ml household bleach and 1260 ml cold water
- Gloves resistant to the disinfectant

Procedure

1. Wipe off surface soil, as required, with a mild detergent solution.

2. Wipe all external surfaces with diluted bleach solution.

3. Wipe all external surfaces with plain water.

CAUTION: **Do not use other disinfecting agents or allow diluted bleach to dry n the ext rnal surfaces or damage may result.**

Preliminary Draft

Keypad

To access the keypad

Touch the desired monitor window; i.e., TEMPERATURE, HEPARIN RATE, PRESCRIBED TIME, ELAPSED TIME, TARGET UF, UF REMOVED, UF RATE.

To enter a value

1. Touch the number button for the first digit in the number.

   The number will be displayed in the keypad window.

2. Touch the number button for the second digit.

   The second digit will be displayed to the right of the first digit.

3. Continue the above steps for the required number of digits.

4. When the correct value is displayed in the keypad window, touch the ENT button to enter the value.

   If a mistake is made in entering a number, touch the RST button. The last set monitor value will be displayed in the keypad window. Now enter the new number as above.

Examples:

To enter a heparin rate of 2.5 ml/h:

1. Touch the HEPARIN PUMP window.

2. Touch the 2 button.

   The keypad window displays:

   ```
   .2
   ```

3. Touch the 5 button.

   The keypad window displays:

   ```
   2.5
   ```

4. Touch the ENT button.

   The HEPARIN PUMP window displays:

   ```
   2.5
   ```

To enter a dialysate temperature of 38.5°C:

1. Touch the TEMPERATURE window.

2. Touch the 3 button.

   The keypad window displays:

   ```
   .3
   ```

3. Touch the 8 button.

   The keypad window displays:

   ```
   3.8
   ```

4. Touch the 5 button.

   The keypad window displays:

   ```
   38.5
   ```

5. Touch the ENT button.

   The TEMPERATURE window displays the actual dialysate temperature.

To enter a prescribed treatment time of 3 hours and 5 minutes:

1. Touch the **PRESCRIBED TIME** or **ELAPSED TIME** window.

2. Touch the 3 button.

   The keypad window displays: | **:03** |

2. Touch the 0 button.

   The keypad window displays: | **:30** |

3. Touch the 5 button.

   The keypad window displays: | **3:05** |

4. Touch the **ENT** button.

   The **PRESCRIBED TIME** window displays: | **3:05** |

   If dialysis has started, the **ELAPSED TIME** window displays the actual elapsed time.

To enter a target fluid loss of 2.35 L:

1. Touch the **TARGET UF** or **UF REMOVED** window.

2. Touch the 2 button.

   The keypad window displays: | **.02** |

3. Touch the 3 button.

   The keypad window displays: | **.23** |

4. Touch the 5 button.

   The keypad window displays: | **2.35** |

5. Touch the **ENT** button.

   The **TARGET UF** window displays: | **2.35** |

   If dialysis has started, the **UF REMOVED** window displays the actual fluid volume removed.

To enter a manual UF rate of 0.13 L/h:

1. Touch the **UF RATE** window.

2. Touch the 1 button.

   The keypad window displays: | **.01** |

3. Touch the 3 button.

   The keypad window displays: | **.13** |

4. Touch the **ENT** button.

   The **UF RATE** window displays: | **.13** |

   If the blood pump is stopped, the UF RATE window displays .0 L/h until the blood pump starts. When the blood pump starts the window displays MANUAL .13 L/h.

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Blood Lines

To load the double blood line clip:

Wide opening end.

top view

side view

a.   b.   c.
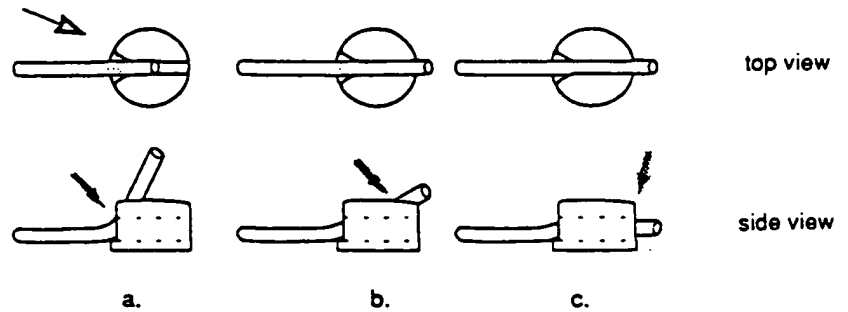
a. With the line between the thumb and clip, press the line into the wide opening end of the slot.

b. With a rolling-sliding motions of the thumb, press the line into the slot.

c. Continue the rolling-sliding motion along the length of the slot.

To remove a line from the double blood line clip:

Wide opening end.

top vi w

side view

a.   b.   c.
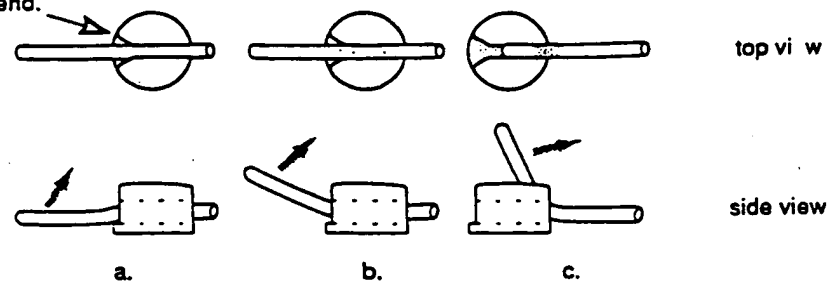
a. Grasp the line on the wide opening end of the slot.

b. Pull the line out away from the machine and toward the slot.

c. Continue pulling in the direction of the slot until the line is free.

To load the single blood line clip:

top view

side view

a.   b.   c.
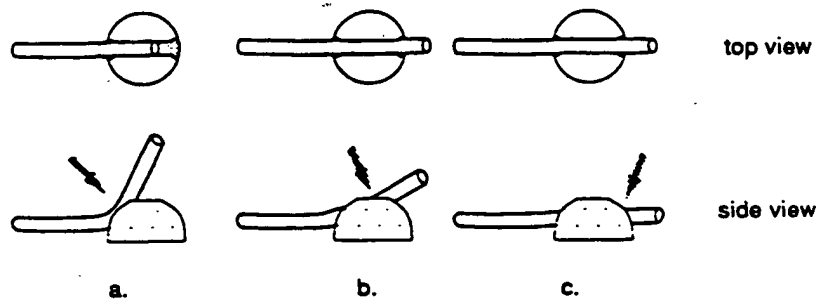
a. With the line between the thumb and clip, press the line into one end of the slot.

b. With a rolling-sliding motions of the thumb, press the line into the slot.

c. Continue the rolling-sliding motion along the length of the slot.

To remove a line from the single blood line clip:

top view

side view

a.   b.   c.
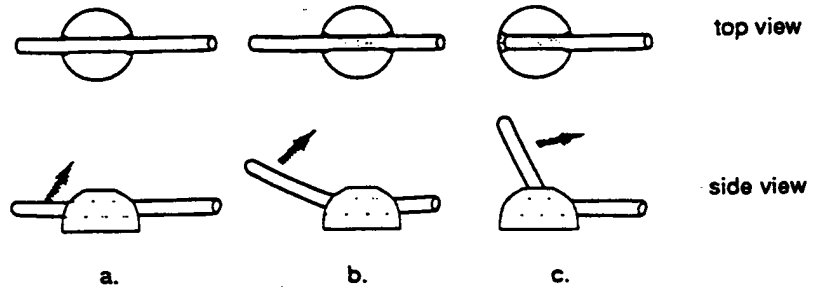
a. Grasp the line on one end of the slot.

b. Pull the line out away from the machine and toward the slot.

c. Continue pulling in the direction of the slot until the line is free.

Preliminary Draft

To load the heparin pump:

Pull arm and turn.

Push arm to allow slide to move.

Push arm to allow slide to move.

Pull arm and turn.

a.   b.   c.   d.   e.

Finger grip depressions

Syringe support

Barrel finger grip

Slide

a. Using the finger grip depressions on the left side of the heparin pump arm, pull the arm out slightly and turn it a quarter turn counterclockwise.

b. Push the lower portion of the arm in slightly as required to allow the slide to be move up or down to accept the syringe plunger.

c. Position the syringe plunger in the slide slot.

d. Push the lower portion of the arm in slightly and move the slide with syringe up until the barrel finger grips contact the lower surface of the syringe support.

e. Using the finger grip depressions on the left side of the heparin pump arm, pull the arm out slightly and turn it a quarter turn clockwise. The arm should cover the barrel finger grips.

To load the air detector:

a.   b.   c.   d.
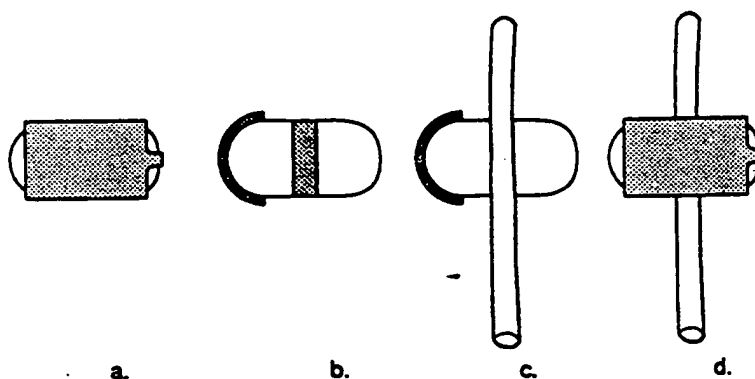
a. Pull the right side of the air detector cover out from the machine.

Preliminary Draft

Special Operations 15

b. Open the cover.

c. Insert the line in the air detector slot.

d. Close the cover.

To load the line clamp:

WARNING Be careful not to stick your fingers in the clamping area of the line clamp.

a.   b.   c.
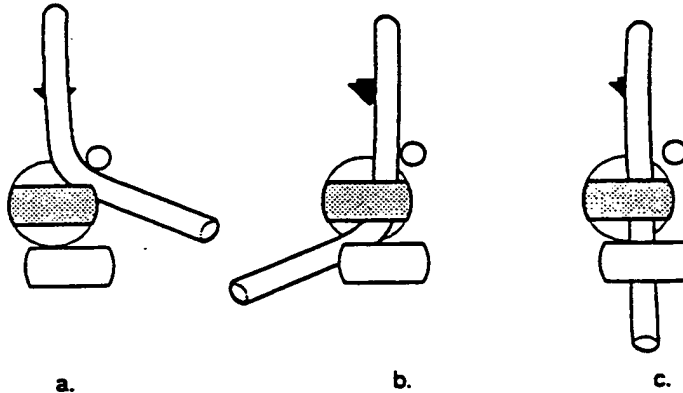
a. Route the blood line to the right between the upper guide and the clamp.

b. Route the blood line to the left between the clamp and the lower guide.

c. Straighten the blood line.

To remove a line from the line clamp:

a.   b.
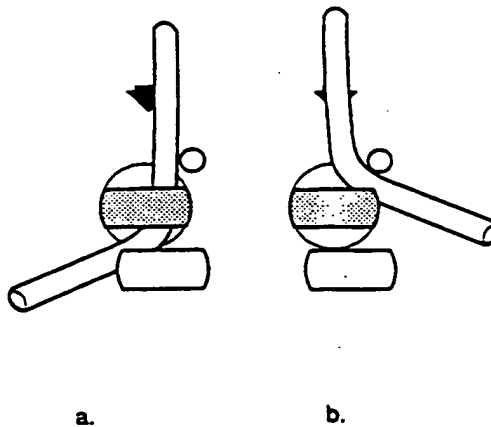
a. Pull the blood line to the left between the clamp and the lower guide.

b. Pull the blood line to the right to remove the line from the clamping area.

Preliminary Draft

To load the blood pump:

Tubing guide

Handle

Small plastic
screw

Tubing clips

a. b. c. d.
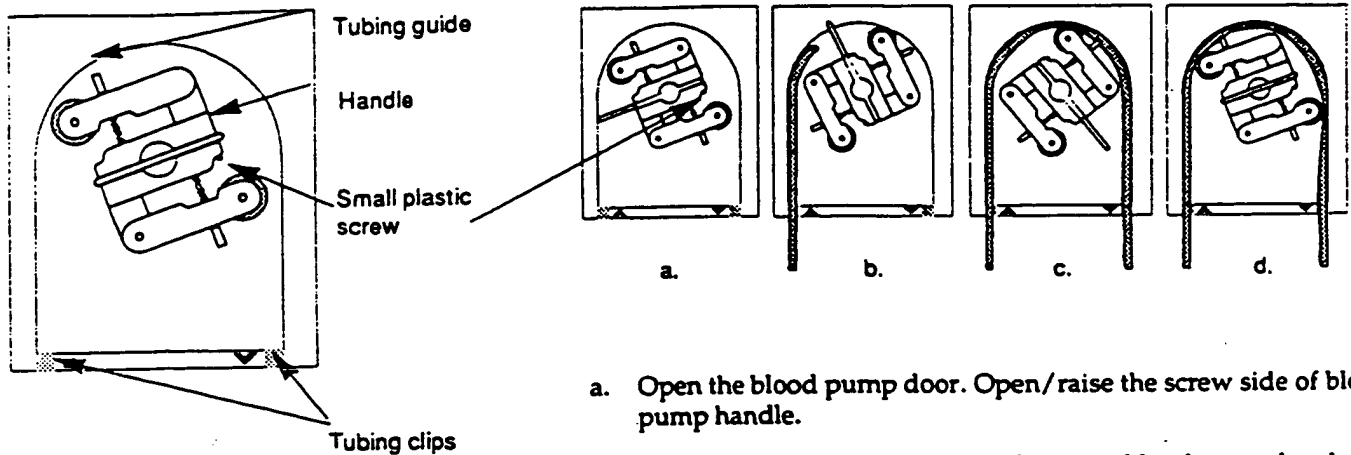
a. Open the blood pump door. Open/raise the screw side of blood
    pump handle.

b. Route the blood pump segment between blood pump head and
    the blood pump wall.

c. Rotate the pump head as required and continue loading the
    pump segment. Make sure the tubing is in the tubing clips and
    between the tubing guides.

d. Fold the handle and close the blood pump door.

Blood Line Layouts

With prepump arterial drip chamber:

Pr liminary Draft
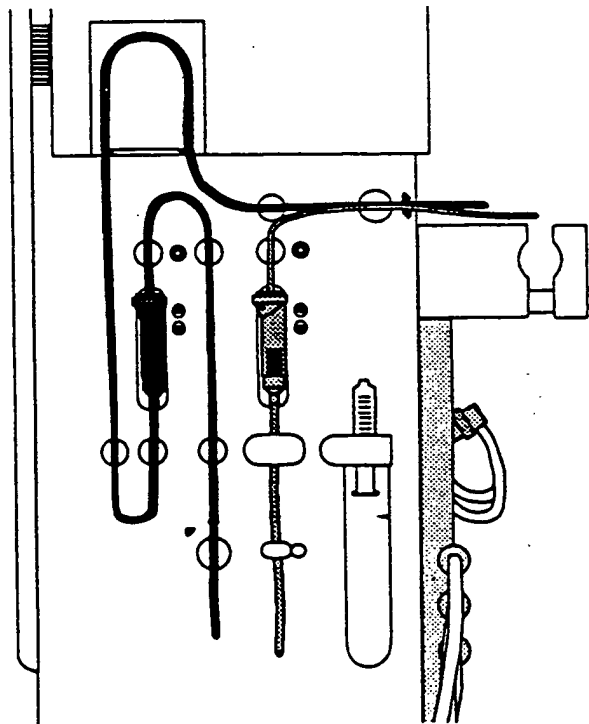
With post pump arterial drip chamber.
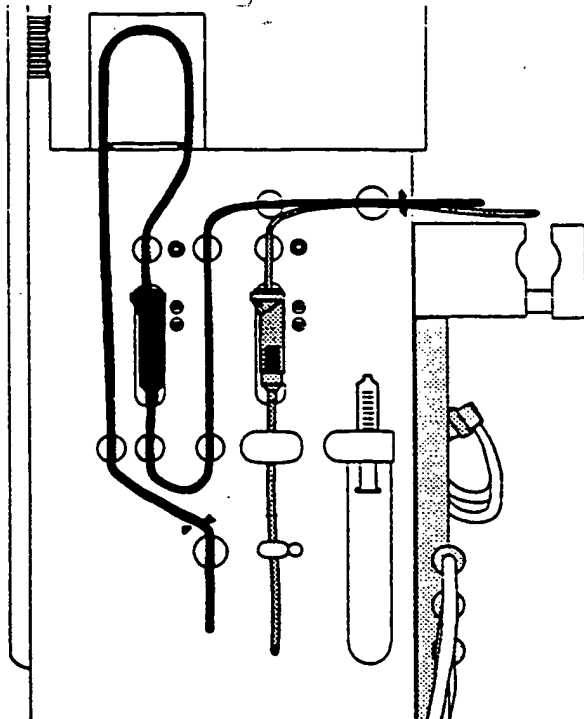
With no arterial drip chamber.

Pr liminary Draft
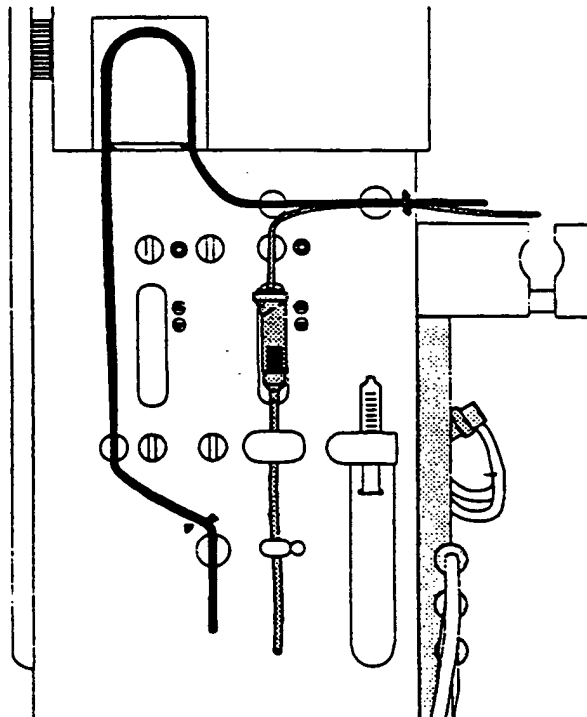
Operation

This section provides the qualified operator with the recommended operating procedure to be used in the preparation and use of the Drake Willock System 1000 Single Patient Delivery System. There are several possible variations of the pre-dialysis rinse procedure depending upon the disinfection method chosen by the attending physician/center; e.g., overnight disinfection with a chemical or pre-dialysis disinfection with sodium hypochlorite. Regardless of the type of disinfection used, all procedures *must* include the verification of an acceptable level of residual disinfectant by a test specific for the disinfectant used, the verification of the proper dialysate and the pre-dialysis system check.

WARNING: **The attending physician is responsible for any changes t the procedures.**

Supplies

- Syringe for withdrawing samples of solution from the dialysate line sample port
- Determination test specific for the chemical disinfectant used
- Dialysate meter (or other test recommended by the attending physician) for testing the dialysate
- 10 or 20 mL syringe for the heparin pump
- Container(s) with enough concentrate for the setup and dialysis time
- Hydrophobic transducer protector(s) ∎ to place on the pressure fitting(s)
- Dialyzer ∎
- Blood lines ∎
- Hemostats, 3
- Saline
- Heparin, if prescribed
- Gloves
- Personal safety supplies required by the facility.

Pre-Setup

- The patient is disconnected from the blood lines and dialyzer.
- The machine is connected to the water supply and the water is off.
- The drain line is in the drain.
- The power cord is plugged in and the mains power switch is on.
- The front panel power switch is off.
- The acid/acetate concentrate line (pink connector) is connected to the acid/acetate rinse port (pink).
- The bicarbonate concentrate line (blue connector) is connected to the bicarbonate rinse port (blue).
- The disinfect line (yellow connector) is connected to the disinfect rinse port (yellow).
- The dialysate lines are connected to the rinse block.

∎ Althin CD Medical recommends the use of Althin CD Medical dialyzers, blood lines and transducer protectors.

Preliminary Draft

Rinse Machine (Before Dialysis)

RINSE

RINSE VERIFY

1. Turn n the water supply.

2. Turn on the machine.

   To turn on the machine, press the power switch.

3. Initiate the Rinse Mode.

   To initiate Rinse, touch the RINSE button, then touch the RINSE VERIFY button (within approximately 3 seconds).

4. Touch the RESET button as required to clear alarms.

5. If the machine had no disinfectant in the fluid path and is to be disinfected, go to step 6.

   If the machine had formaldehyde or another disinfectant in the fluid path, go to step 7.

6. Disinfect the fluid path, as required.

   Refer to Disinfect Machine Fluid Pathway in the Special Operations section of this manual for specific disinfection procedures.

7. Rinse the disinfectant from the fluid path, as required.

   To rinse the fluid path, continue rinsing the fluid path with water for approximately 15 minutes.

   Note: The rinse out time may be reduced by increasing the dialysate flow rat .

8. Test the rinse solution for residual disinfectant, as required.

   To test for residual disinfectant:

   a. Withdraw a sample of the rinse solution from the dialysate lines.

   b. Perform a residual disinfectant determination test on the sample.

WARNING: To ensure that the disinfectant level in the dialyzer circuit is below a level acceptable for patient safety, sample the rinse solution in the dialysate lines.

Make sure that the determination test is specific for the disinfectant used.

Make sure that the determination test shows a sufficiently low level of disinfectant in the rinse solution before going on to th next step. Refer to the attending physician's directives for the acceptable limit and the AAMI standard for hemodialysis.

   c. Remove the disinfectant warning sign from the machine, as required.

9. Connect the concentrate(s).

WARNING: Make sure there is an adequate supply of concentrate(s) in the containers(s) for the entire dialysis treatment including setup.

   For acetate dialysis:

   a. Connect the acid/acetate concentrate line (pink connector) to a full container of acetate concentrate.

   For bicarbonate dialysis:

   a. Connect the acid/acetate concentrate line (pink connector) to a full container of acid concentrate.

Preliminary Draft

L2400-356 Rev. N 1/14/91

b. Connect th bicarbonate concentrate line (blue c nnector) to a full container of bicarbonate concentrate.

10. **After the c nductivity and temperature stabilize, initiate the Self Test Mode.**

If there are any xtracorporeal alarms, touch the **RESET** button to clear the alarms and access the **TEST** button.

Do not manually turn on the blood pump during Self Test or a blood pump overspeed alarm will occur.

Make sure the machine is not in manual bypass or the self test will fail.

To initiate Self Test, touch the **TEST** button.

The machine will prompt the operator for the following information:

At the beginning of Self Test,

a. **BLD PRESS TEST: ARE PRESS LUERS PLUGGED?**

If the blood lines have been set up, make sure the pressure monitor lines are clamped with hemostats, then touch the YES button.

If the blood lines have not been set up, make sure the pressure luers are plugged then touch the YES button.

b. **VERIFY AUDIO ALARM/ALARM LAMP?**

If there is an audible alarm and the main alarm lamp is flashing, touch the YES button.

At the end of Self Test,

c. **IS CONDUCTIVITY CORRECT?**

Test the dialysate.

To test the dialysate:

1) Obtain a sample of dialysate from the dialysate line sample port.

2) Perform a dialysate determination test on the sample. Make sure that the instrument used to perform this test has been calibrated for accuracy.

3) Make sure that the conductivity value is appropriate for the concentrates being used.

4) If the displayed conductivity matches the independent test value, touch the YES button.

If the displayed conductivity does not match the independent test value, touch the NO button and refer to the Problem Solving section of this manual.

d. **ARE PRESSURE LUERS VENTED?**

Unplug/unclamp the pressure luers.

11. **Set up the dialyzer and blood lines, as required.**

12. **Initiate the Prime Mode.**

To initiate Prime, touch the PRIME button.

13. **Prime the dialyzer and blood lines.**

Refer to your center's procedures for detailed actions.

T prim the dialyzer and blood lines:

a. Touch the ARMED / DISARM button to disarm the extracorporeal alarms.

TEST

PRIME

ARMED/
DISARM

Pr liminary Draft

RESET

b. Touch the RESET button, as required.

c. Set the blood pump flow rate.

d. Turn n the blood pump, as required.

e. Set a manual UF rate, as required.

To connect the dialyzer connectors to the dialyzer:

a. Press the manual bypass button.

b. Connect the dialyzer connectors to the appropriate dialyzer ports.

c. Press the manual bypass button.

To load the heparin pump:

a. Fill the syringe with heparin.

b. Connect the heparin line to the syringe.

c. Clamp the heparin line but do not prime the line.

14. **Set the treatment parameters; i.e., prescribed dialysis time and desired fluid loss.**

To set the prescribed dialysis time:

a. Touch the PRESCRIBED TIME window.

b. Use the keypad to input the prescribed dialysis time in hours and minutes.

c. Touch the keypad ENT button to enter the prescribed dialysis time as displayed in the keypad window.

To set the desired fluid loss:

a. Touch the TARGET UF window.

b. Use the keypad to input the desired fluid loss in liters.

c. Touch the keypad ENT button to enter the fluid loss as displayed in the keypad window.

15. **Turn off the blood pump, as required.**

Start Dialysis

START

Note: If an extracorporeal alarm exists, clear and reset the alarm before touching the START button.

1. **Touch the START button (button #5).**

Use your center's procedures for detailed actions, beginning dialysis includes turning on the blood pump and setting the correct flow rat .

If a UF rate lower than the calculated rate is desired at treatment initiation, enter a low manual UF rate before turning on the blood pump. Otherwise the calculated UF rate will start as soon as the blood pump starts.

Note: When the blood pump is off and a manual rate is entered, the UF rate is displayed as OFF. When the blood pump starts, the UF rate automatically goes to the manual UF rate entered.

To initiate heparin infusion:

a. Unclamp the heparin line.

b. Set the heparin infusion rate.

1) Touch the HEPARIN PUMP window.

Preliminary Draft

  2) Enter the desired infusion rate in milliliters per hour using the keypad.

 c. With the blood pump on, give a heparin bolus.

  1) Touch the HEPARIN PUMP window.

  2) Then touch the BOLUS button.

Discontinue Dialysis

1. **Discontinue dialysis.**

Return the extracorporeal blood to the patient, turn off the blood pump, clamp the blood lines and disconnect the blood lines from the patient.

If a minimum UF rate (other than zero) is desired for returning the patient's blood after the target UF is reached:

a. Enter a new target UF higher than the current UF removed.

b. *Immediately* enter the specific manual UF rate desired.

Use your center's procedure for detailed actions.

WARNING: **Make sure that the patient is disconnected from the dialyzer and blood lines before going on to the next step.**

2. **Record the treatment data from the data report before initiating rinse.**

Note: Starting the Rinse Mode erases portions of the data report.

3. **Disconnect the dialysate lines from the dialyzer and c nnect them to the machine rinse block.**

a. Press the manual bypass button.

b. Connect the dialyzer connectors to the rinse block.

c. Press the manual bypass button.

4. **Start the Rinse Mode.**

Prepare Machine for Another Patient (if required)

1. Make sure there is an adequate supply of concentrate(s) in the containers(s) for the entire dialysis treatment including setup.

2. Continue the predialysis preparation by completing Rinse Machine (Before Dialysis) steps 10 through 15 .

Rinse Machine (After Dialysis)

1. **Connect the concentrate lines to the machine.**

After acetate dialysis, connect the acid/acetate concentrate lin (pink connector) to the acid/acetate rinse port (pink).

After bicarbonate dialysis, connect the bicarbonate concentrate line (blue connector) to the bicarbonate rinse port (blue), then connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

2. **Rinse the machine with water for 10 minutes.**

Note: Higher dialysate flow rates will shorten the rinse time.

DATA REPORT

RINSE

RINSE VERIFY

CAUTION: Be sure to rinse the machine with water before introducing new chemicals into the fluidpath. Otherwise, precipitates or other deposits in the flowpath may re ult from reactions f various chemical mixtures.

3. If the machine is to be disinfected, refer to Disinfect Machine Fluid Pathway in the Special Operations section of this manual.

    If the machine is to be turned off, go tc step 4.

4. Turn off the machine.

    To turn off the machine, press the front panel power switch. Turn off the mains power switch at night.

5. Turn off the water supply.

Theory

The System 1000 is a dialysis delivery system that combines the functions necessary for a dialysis treatment with volumetric ultrafiltration control, bicarbonate dialysis and sequential ultrafiltration.

The normal progression of the machine operation for a dialysis treatment is Power On, Standby, Rinse, Self Test, Prime, and Dialyze. After dialysis (and the patient disconnected), the treatment data is recorded, the fluid path is rinsed, and the fluid path is disinfected as required.

Standby Mode

When turned on, the machine powers up and enters the Standby Mode. Although this is a "safe" mode (the blood pump will not operate and the dialyzer circuit is bypassed), the machine is waiting for instruction from the operator.

Rinse Mode

Rinse is initiated by touching the RINSE then RINSE VERIFY buttons. Rinse is provided to heat the dialysate, introduce chemicals into the machine (either dialysate concentrates or disinfectants) or rinse chemicals from the machine. The audio alarm is muted except for power fail and no dialysate flow alarms. The line clamp remains open and the blood pump will operate as long as the dialyzer connectors are on the rinse block. This gives the operator the option of priming the blood side of the dialyzer during Rinse. The air detector and blood leak detector alarm machine functions are automatically disabled. The arterial pressure alarm limits are automatically set to –400 and +600 mmHg. The venous pressure alarm limits are automatically set ±200 mmHg around the pressure indicated 10 seconds after the blood pump starts, stops or the blood pump rate is changed.

After rinsing the fluid path with water, the concentrate(s) is/are connected to the machine. When the conductivity and temperature are within normal operating range and stable, the operator initiates the Self Test routine by touching the SELF TEST button.

Self Test Mode

During Self Test, the machine automatically performs the machine related pre-dialysis "operator tests." The essential alarms, monitors and functions are checked during rinse, such as the conductivity alarms, UF system, arterial and venous pressure monitoring systems, etc. At the beginning of Self Test, the operator is prompted to verify that the arterial and venous pressure luers are plugged, an audio alarm occurs, and the main alarm lamp flashes. A few minutes later, at the end of Self Test the operator is again prompted: IS CONDUCTIVITY CORRECT? At this time the operator verifies the conductivity by withdrawing a sample of dialysate from the dialyzer circuit sample port and performing an independent conductivity check with an external meter. The primary conductivity alarm limits are automatically set by the machine to ±5% of the indicated conductivity value when the YES button is touched to verify the dialysate conductivity.

Prime Mode

Upon successful completion of the Self Test, the operator initiates the Prime Mode by touching the PRIME button. During Prime, the extracorporeal alarm may be disarmed by the operator to allow the

removal of air from the dialysate and blood sides of the dialyzer. The machine will remain in disarm for approximately 5 minutes, permitting priming of the blood lines and dialyzer. While the alarms are disarmed, the arterial pressure alarm limits are –400 and +600 mmHg, the venous pressure alarm limits are ±200 around the indicated venous pressure 10 seconds after the blood pump is turned on, off or the rate changed. The air and blood leak detector machine responses are disabled (except for the visual indicator).

While the extracorporeal alarms are armed, the alarms are active and the arterial and venous pressure alarm limits are ±50 mmHg around the indicated pressure 10 seconds after the blood pump is turned on or off or the rate is changed. The operator sets the prescribed dialysis time and the target fluid loss in the Prime Mode. However the manual UF rate set in Prime (0.01 to 0.5 L/h) will override the calculated UF rate until the START button is touched and the treatment is begun.
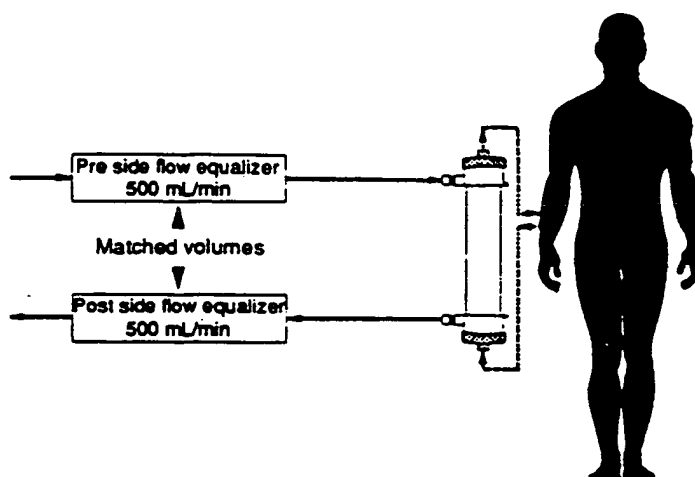
Dialyze Mode

The START button is touched to start the Dialyze Mode. The patient is connected and the dialysis treatment is performed in the Dialyze Mode. The machine automatically calculates the UF rate from the operator set PRESCRIBED TIME and TARGET UF. The ELAPSED TIME and the UF REMOVED are recorded and displayed. The alarms are functional. The arterial alarm limits open, for approximately 10 seconds, to –400 and +600 when the blood pump is started or the blood pump rate is changed. The venous alarm limits open, for approximately 10 seconds, to ±200 mmHg around the indicated pressure. After the 10 seconds, the alarm limits automatically set to ±50 mmHg of the indicated pressure. The minimum low venous alarm limit is +10 mmHg. When the blood pump is manually turned off, the arterial and venous alarm limits automatically open. The TMP alarm limits open to ±200 mmHg around the indicated TMP, for approximately 90 seconds, when the blood pump is started, the blood pump rate is changed or the UF rate is changed. After the 90 seconds, the alarm limits automatically set to ±35 mmHg of the indicated TMP. The minimum low TMP alarm limit is –80 mmHg. The maximum high TMP alarm limit is +500 mmHg. The arterial and venous alarm limits may be manually set to ±50 mmHg and the TMP alarm limits may be manually set to ±35 mmHg of the indicated pressures by touching the SET LIMITS button.

When the target fluid loss is reached, the main alarm lamp flashes, the audio alarm sounds five quick beeps, the UF REMOVED alarm indicator flashes and the UF rate goes to 0 L/h.
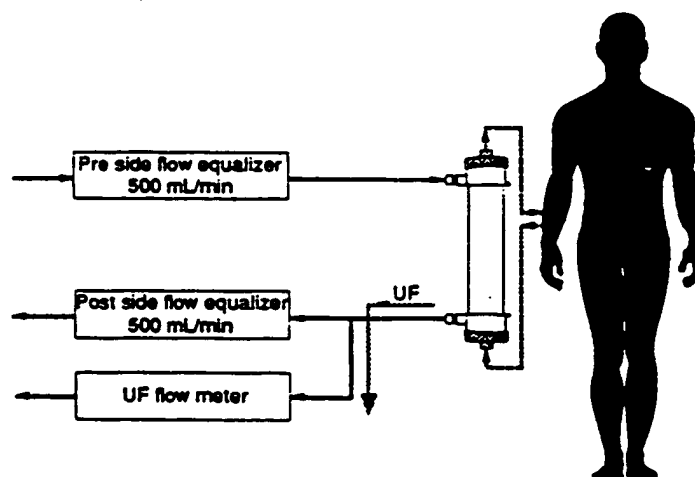
After the treatment is completed and the patient disconnected from the dialyzer and blood lines, the treatment data should be recorded from the data report prior to entering the Rinse Mode. While the dialyzer connectors are on the rinse block, the Rinse Mode is initiated. The machine may now be prepared for another patient or rinsed with water in preparation for disinfection and shutdown.

Preliminary Draft

Ultrafiltration

The System 1000 accurately controls fluid removal. A volumetric flow equalizer controls/and balances dialysate to and from the dialyzer. The volume of fresh dialysate measured and delivered to the dialyzer by the pre side of the flow equalizer is equal to the volume of used dialysate removed from the dialyzer by the post side of the flow equalizer.

```
┌──────────────────────┐
│ Pre side flow equalizer│
│      500 mL/min       │
└──────────────────────┘
          ▲
   Matched volumes
          ▼
┌──────────────────────┐
│ Post side flow equalizer│
│      500 mL/min       │
└──────────────────────┘
```

Between the balanced pre and post flow equalizers are two openings. One is the dialyzer membrane surface, the other is the UF flow meter. The UF flow meter is controlled by the electronics to meter a measured amount of used dialysate from the dialysate compartment. The fluid measured by the UF flow meter causes an identical amount of fluid to be pulled from the blood side of the dialyzer. Since the flow equalizer balances the dialysate flowing to and from the dialyzer, the fluid going through the UF flow meter is equivalent to the ultrafiltrate removed from the patient.

```
┌──────────────────────┐
│ Pre side flow equalizer│
│      500 mL/min       │
└──────────────────────┘

┌──────────────────────┐              UF
│ Post side flow equalizer│
│      500 mL/min       │
└──────────────────────┘

┌──────────────────────┐
│     UF flow meter     │
└──────────────────────┘
```

The flow through the UF flow meter is displayed in the UF RATE window and the data report screen. The fluid that passes through the UF flow meter is not entirely ultrafiltrate. It is volumetrically equivalent to the patient's ultrafiltrate. The total volume of fluid removed from the patient is continuously displayed throughout the treatment in the UF REMOVED window.

Ultrafiltration control steps:

How to enter a UF rate.

1. During Prime, the operator enters the prescribed treatment time (in hours and minutes) in the PRESCRIBED TIME window and the desired fluid to be removed (in liters) in the TARGET UF window.

2. The machine automatically calculates the hourly UF rate.

Note:

The manual UF rate controls the machine in the Prime Mode. Once th Dialyze Mode is started the calculated UF rate is displayed and controls the machine.

3. The desired volume of fluid is removed from the patient's blood.

4. The total volume of fluid removed (in liters) is displayed continuously in the UF REMOVED window.

The operator may manually override the calculated UF rate by manually entering the desired UF rate once dialysis has started.

Venous and Arterial Pressure Monitors

The monitors indicate pressures in the extracorporeal drip chambers. Whenever the pressure indicator goes outside of the alarm limit window for more than 3 seconds the monitor goes into alarm.

During a venous or arterial blood pressure alarm, the main alarm lamp flashes, the appropriate alarm indicator flashes, the audio alarm sounds, the blood pump stops, the line clamp occludes the venous blood line and the UF rate automatically goes to 0 L/h.

Connected to the venous and arterial luer connectors is an automatic level adjust pump, this pump is used to raise or lower the level of blood in the extracorporeal blood line drip chambers. In Dialyze when the level adjust pump is used, the arterial and venous pressure alarm limits automatically open for approximately 10 seconds. After the 10 seconds they automatically reset to ±50 mmHg of the indicated pressures.

During the standby and rinse modes, the arterial pressure alarm limits are wide open; i.e., –400 to +600 mmHg. The venous pressure alarm limits are set ±200 mmHg around the indicated venous pressure at the beginning of the rinse mode or 10 seconds after the blood pump rate is changed.

During the prime mode (with the extracorporeal alarms armed) and the dialyze mode; when the blood pump is started, manually turned off or rate changed, the arterial pressure alarm limits open to –400 to +600 mmHg and the venous pressure alarm limits open to ±200 mmHg around the appropriate indicated pressure. After 10 seconds the arterial and venous alarm limits close to ±50 mmHg around the respective pressure with the low venous alarm limit being no less than +10 mmHg.

Preliminary Draft

Heparin Pump

The heparin pump is a syringe pump that infuses heparin into the blood flow circuit at an operator-adjustable rate during the prime and dialyze modes. It operates only when the blood pump is on. The heparin pump alarms when the motor is infusing heparin faster than the setting on the device. It also alarms when the heparin syringe is empty or the motor is stalled.

Install the heparin syringe during the prime mode. The heparin pump rate may be set during the Prime or Dialyze Modes. The heparin pump rate may be set from 0 to 5.5 ml/h. Entering a non-zero heparin rate turns on the pump. Entering a zero rate turns off the pump. The words ON and OFF will appear above the HEPARIN PUMP window appropriately.

A heparin bolus may be given by touching the HEPARIN PUMP window then the BOLUS button. The bolus volume is displayed on the BOLUS button. The bolus volume may be calibrated and is displayed on the data report and bolus button.

The heparin pump may set by a qualified service technician to be used with either 10 or 20 ml capacity syringes. The type of syringe for which the machine is calibrated, is indicated in the data report.

Dialysate

Dialysate Flow Rate

The dialysate flow rate may be set from 500 to 1000 ml/min in 100 ml increments by touching the DIALYSATE FLOW RATE window to display the desired flow rate, then touching the FLOW VERIFY button. At startup the flow rate defaults to 500 ml/min.

Dialysate temperature

The dialysate temperature may be set between 35.5 and 39°C. When the machine is turned on, the default temperature setting is 37°C. To enter a different temperature; the operator touches the TEMPERATURE window, enters the desired value in the keypad then touches the keypad ENT button. To restore the existing set temperature, touch the keypad RST button then the ENT button.

Dialysate Preparation/Proportioning

The machine may be set by a qualified service technician to accept dialysate concentrates from one of several mixing ratios. The default proportion is either acetate concentrate requiring 34 parts water to 1 acetate concentrate proportioning, or bicarbonate and acid concentrates requiring 34 water to 1 acid concentrate to 1.8 bicarbonate concentrate containing 59 mEq/L sodium in the bicarbonate concentrate.

The 34:1 or 34:1:1.8 proportioning ratio used by the machine for a particular treatment is determined by the placement of the concentrate lines at the start of the self test routine. If only the acid/acetate concentrate port interlock is open, the machine will proportion for acetate dialysis. If both the acid/acetate and bicarbonate concentrate lines are open, the machine will proportion

for bicarbonate dialysis. In order to change the proportioning ratio the machine *must* go into the Rinse Mode.

Other availabe proportioning ratios include 32.77 parts water to 1 part acid concentrate to 1.23 parts bicarbonate concentrate, and 42.6 parts water to 1 part acid concentrate to 1.4 parts bicarbonate concentrate.

Treatment Data

The System 1000 records treatment parameters and data. This data may be obtained by touching the MENUS then DATA REPORT buttons.

Data report information includes prescribed treatment time, elapsed treatment time, treatment time remaining, target UF, UF removed, UF remaining, total blood processed and total heparin infused.

The total heparin infused includes the heparin infused during the Prime and Dialyze Modes.

Prescribed Treatment Time	=	h:m
Elapsed Treatment Time	=	h:m
Treatment Time Remaining	=	h:m
Target UF	=	L
UF Removed	=	L
UF Remaining	=	L
Total Blood Processed	=	L
Total Infused Heparin	=	ml
Syringe *type*	Bolus *size*	
UF rate		
Concentrate type		
Date	Time *of day*	
Statement about calculated UF rate.		

Sample Data Report

Keypad

Keypad window
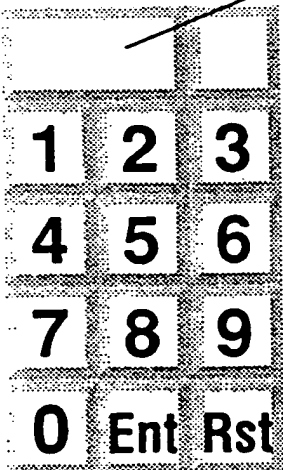
The operator uses a keypad to enter the heparin pump rate, the dialysate temperature, the prescribed treatment time, the target fluid loss, and the manual UF rate as required. The keypad appears when the appropriate monitor window is touched.

A value is entered by touching the appropriate number buttons. The value is displayed in the keypad window. To enter the displayed value, the ENT button is touched. If a mistake is made, touch the RST button to restore the previously set value.

If no change to the set value is required, the operator may touch the RST then ENT buttons or wait approximately 15 seconds for the keypad to disappear without changing the set value.

Preliminary Draft
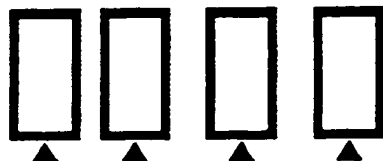
Alarm Matrix

Monitor/alarm	Visual Indication	Audible Indication	Silence available?	Reset required?	Machine action
air detector	displayed in flashing alarm window main alarm lamp flashes	sounds	yes	yes	blood pump stopped heparin pump stopped line clamp clamped UF rate 0 L/h (off) elapsed time stopped
blood leak detector	displayed in flashing alarm window main alarm lamp flashes	sounds	yes	yes	blood pump stopped heparin pump stopped line clamp clamped UF rate 0 L/h (off) elapsed time stopped
no supply	displayed in flashing alarm window main alarm lamp flashes	sounds	yes	no	no control function
venous pressure	alarm indicator flashes main alarm lamp flashes ALARM	sounds	yes	yes	blood pump stopped line clamp clamped UF rate 0 L/h (off) elapsed time stopped
arterial pressure	alarm indicator flashes main alarm lamp flashes	sounds	yes	yes	blood pump stopped line clamp clamped UF rate 0 L/h (off) elapsed time stopped
conductivity (primary)	alarm indicator flashes main alarm lamp flashes ALARM	sounds	yes	no	bypass
backup conductivity	alarm indicator flashes main alarm lamp flashes BACKUP	sounds	yes	no	bypass
temperature (primary)	alarm indicator flashes main alarm lamp flashes ALARM	sounds	yes	no	bypass
backup temperature	alarm indicator flashes main alarm lamp flashes BACKUP	sounds	yes	no	bypass
transmembrane pressure	alarm indicator flashes main alarm lamp flashes	sounds	yes	no	no control function

AIR DETECTED

BLOOD LEAK DETECTED

NO DIALYSATE FLOW

Monitor/alarm	Visual Indication	Audible Indication	Silence available?	Reset required?	Machine action
heparin pump overspeed	alarm indicator flashes main alarm lamp flashes OVERSPEED	sounds	yes	yes	shuts off heparin pump
heparin pump overpressure	alarm indicator flashes main alarm lamp flashes OVERPRESSURE	sounds	yes	no	shuts off heparin pump
UF removed (target UF obtained)	alarm indicator flashes main alarm lamp flashes	sounds (5 rapid beeps)	yes	no	UF rate 0 L/h (off)
Elapsed time (prescribed time met)	alarm indicator flashes main alarm lamp flashes	sounds (5 rapid beeps)	yes	no	UF rate 0 L/h (off)
power off	control panel and all lamps off	sounds	yes	no	no control function
bypass	displayed in bulletin window main alarm lamp flashes	sounds	yes	call service technician	machine shutdown occurs instructs operator to turn off power.
blood pump stop	displayed in bulletin window main alarm lamp flashes	sounds	yes	no	no control function

BYPASS HAS FAILED

BLOOD PUMP STOP ALARM

Preliminary Draft

Acid/acetate rinse port

Acid/acetate concentrate line

Bicarbonate concentrate line

Bicarbonate rinse port

Disinfect line

Disinfect rinse port

Dialysate line connector
holders (rinse block)
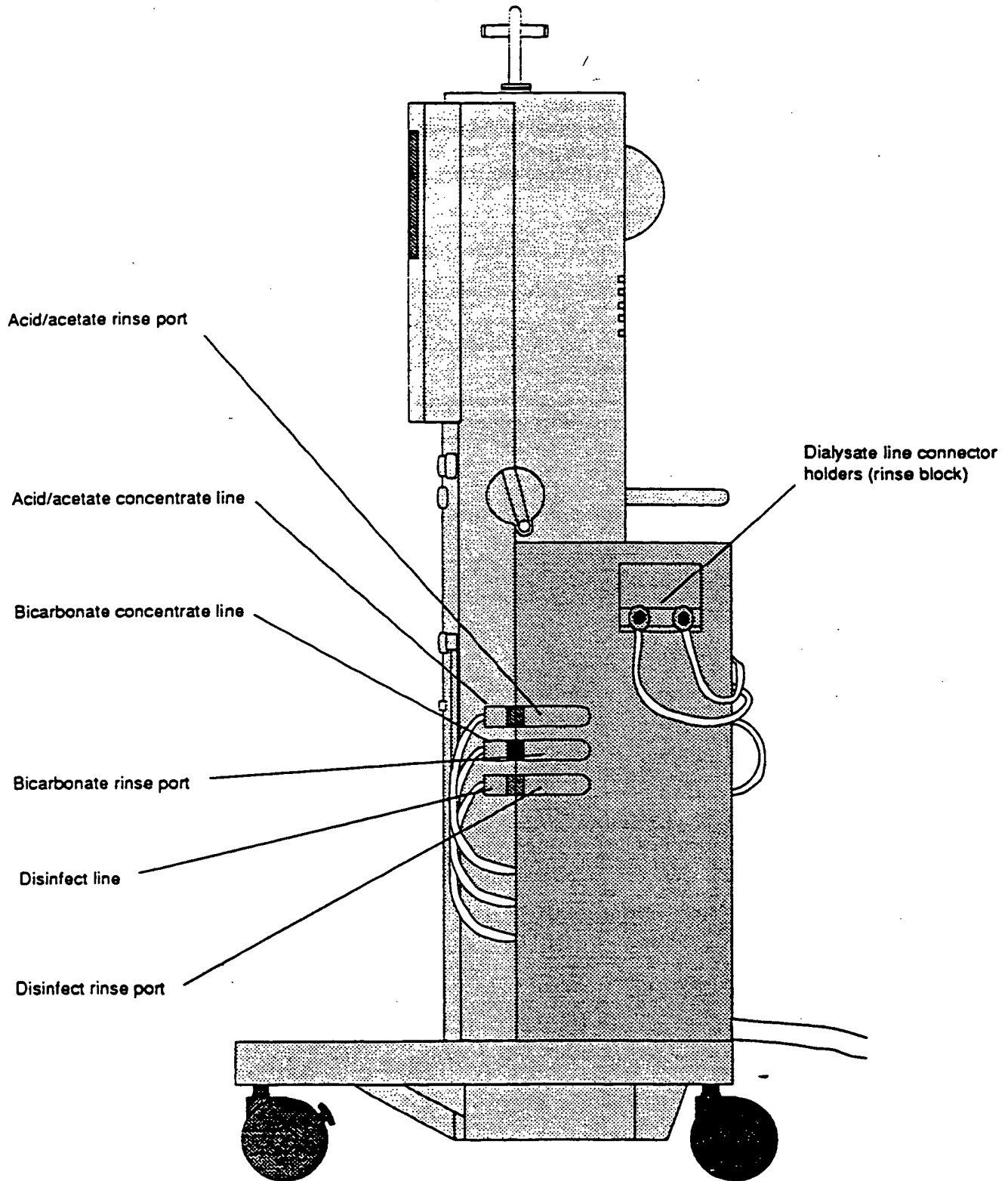
Dialysate lines and connectors

Attach to the dialyzer dialysate inlet and outlet port during dialysis to deliver fresh dialysate and remove used dialysate. The connectors are color-coded to indicate the dialysate flow direction and aid in connection to the dialyzer. The blue connector is connected to the line that delivers fresh dialysate to the dialyzer. The red connector is connected to the line that takes used dialysate from the dialyzer.

Handle

Is used to push or position the machine.

Dialysate line sample port (post dialyzer)

Permits sampling of the dialysate leaving the dialyzer.

Ultrafiltrate line

May be disconnected and placed in a graduated cylinder for verification of ultrafiltrate removed.

Preliminary Draft

Handle

Dialysate lines
and connectors

Dialysate line sample port

Ultrafiltrate line
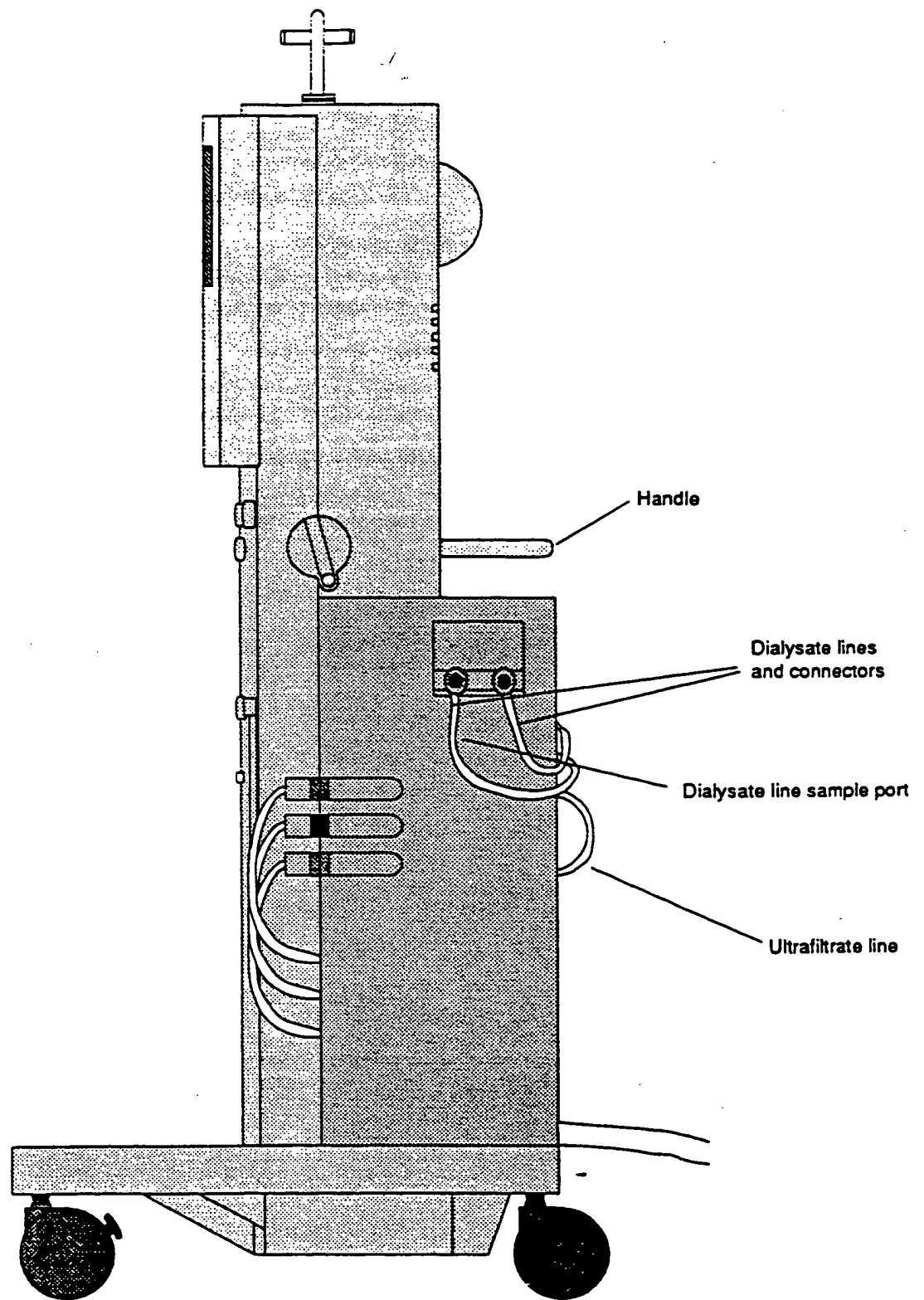
Back

Hour meter

Records and displays the elapsed time the machine has operated.

Blood leak detector

Monitors the post dialyzer dialysate for blood.

RS232 connector

Provides a means for connection of the machine to a computer or computerized system.

Mains power switch

Turns the mains power to the machine on and off. Turn this switch off at the end of the day.

Power cord receptacle

Accepts the power cord. The other end of the cord plugs into an appropriate (hospital grade) wall outlet.

Preliminary Draft

Hour meter

Blood leak detector

RS232 connector

Mains power switch

Power cord receptacle

Preliminary Draft
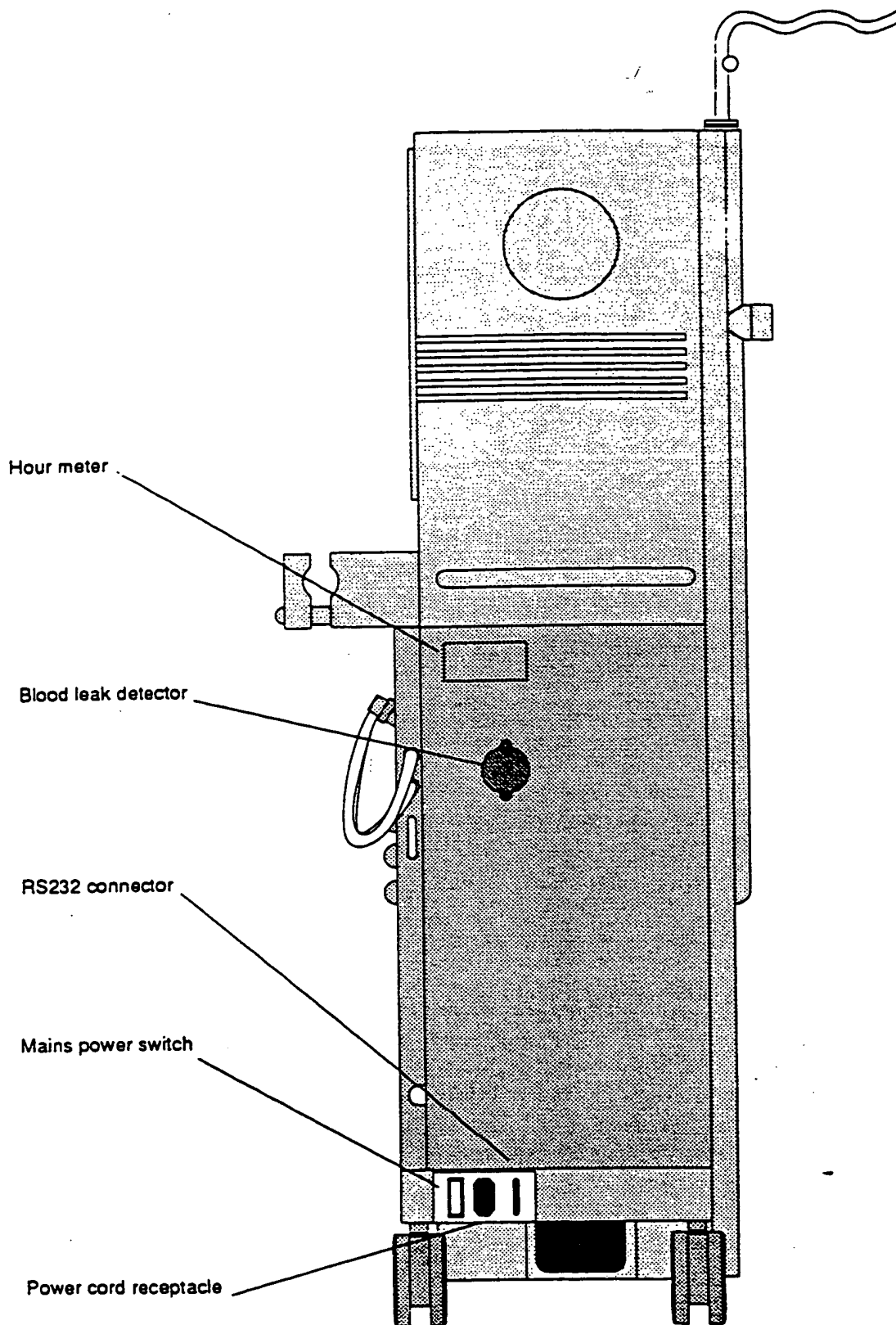
System 1000 Development

Architecture

General Description

Main Controller Hardware (Host)

The System 1000 machine is controlled by an 80XX microprocessor (uP) and three 8040 microcontrollers (uC). The 80XX uP is located on an IBM PC/AT compatible motherboard, with its primary responsibilities being:

- User interface (CRT display and touch screen)
- State machine control (Rinse, Prime, Dialyze,...)
- Microcontroller communications
- Conducting self tests
- Calibrations

The firmware for the 80XX uP is located on the Memory Board, which plugs into the motherboard. The Memory Board can hold up to 384K of ROM (read only memory). In addition it also contains 8K of nonvolatile static RAM (random access memory) (for calibrations and machine parameters), a memory card interface, an RS-232 interface, and a time of day clock. The 80XX uP has access to 256K of dynamic RAM located on the motherboard.

The 80XX uP controls the operation of the machine through its connection to the following additional boards which are plugged into the motherboard:

- EGA display board
- Touch screen interface board
- Blood Pump system controller board
- UF/Proportioning system controller board
- I/O system controller board
- RS-232 board (optional for patient blood pressure monitor)

Main Controller Software (Host)

The host control program is written in the 'C' programming language. The program source code is compiled, linked and loaded into programmable read only memory. This memory resides on the embedded hardware system memory board.

The purpose of the host control program is to:

- Gather data from the Input/Output, Blood Pump and Ultrafiltration controller sub-systems, and output control functions to the various controller sub-systems.
- Input data from user interface touch screen.
- Monitor the data for violation of alarm limits and unsafe operating conditions, and to set the appropriate program alarm condition indicators;

- Evaluate the data to determine the current operating state of the control program, i.e. Standby, Rinse, Self Test, Prime and Dialyze.
- Update the display data to the CRT portion of the user interface.

Blood Pump Control System

Five subsystems are controlled or monitored by the blood pump controller. They are:

- Blood pump
- Blood pressure measurement (arterial, venous and expansion chamber)
- Heparin delivery
- Level adjust
- Ambient temperature

Blood Pump Controller

The purpose of the blood pump controller is to supply power to the blood pump motor such that the pump head will turn and pump at a rate selected by the operator.

The blood pump controller system consists of the following major components:

Description	Location
User parameter entry	Host controller
Software Speed Error Control	Bld Pmp Controller
Hardware Speed Error Control	BP Power Board
Optical speed sensor	On motor shaft
Motor Power Driver Circuitry	BP Power Board

The operator enters the desired blood pump rate information on the video screen (CRT) touch panel. The host controller (80XX microprocessor) converts this information to the appropriate motor rate which it then sends to the Blood Pump controller (8040) on the Blood Pump Controller board. The 8040 controller converts the motor rate information to an analog level, which is fed to a motor speed control IC (LM2917-8) on the Blood Pump Power board.

An optical speed sensor is mounted on the rear shaft of the blood pump motor, with an LED being positioned on one side of the shaft, and a photo transistor on the opposite side. The shaft has two holes drilled through it, with each hole being perpendicular to the shaft and to each other. This results in four optical pulses received per shaft revolution.

This tachometer signal is monitored by both the LM2917-8 and the 8040 controller. The LM2917-8 provides quick responding speed control by comparing the motor speed with the desired speed information from the 8040. The result of this comparison is an error signal which provides an input to the motor power driver circuit.

The motor power driver provides a +24 V pulse width modulated drive to the motor at a frequency of approximately 30 KHz. This drive

is current limit protected, to prevent damage in the event of a stalled motor.

The 8040 compares the tachometer motor speed information with the desired speed commanded by the 80XX and corrects the level provided to the LM2917-8 accordingly. In this way the 8040 guarantees the ultimate accuracy of the pump, with the LM2917-8 circuit not requiring any calibration. In addition, the 8040 can monitor for control problems, such as under speed or over speed, which may result from failures in the LM2917-8 or motor drive circuitry.

The 8040 also monitors the motor speed independent of the tachometer signal using the motor's back EMF. Periodically (every 0.5 second) the motor drive is turned off for approximately 6 millisecond and the voltage at the motor terminals is measured. Though this does not result in as precise an indication as the tachometer signal, gross failures can be determined, such as when the tachometer signal is lost.

Blood Pressure Measurement

The blood pressure measurements include the venous, arterial and expansion chamber (for Single Needle treatment) pressures. All three measurement systems include identical hardware. Each pressure is sensed by a SenSym SCX15 gauge sensing pressure transducer mounted to the Blood Pump Power board. Each transducer is connected to a differential amplifier designed to provide a measurement range from −400 to +600 mmHg. The output of each amplifier drives an A/D input channel of the Blood Pump Control system, at which point it is converted to a 10 bit digital value. The calibration of the each pressure input is handled entirely in software, requiring that the design of each amplifier guarantee that its output remain within the A/D input range of 0 to +5 V over the input pressure range and over all component tolerances.

Heparin Delivery

Heparin delivery is accomplished by stepping a stepper motor which rotates the pinion of a rack and pinion mechanism. The pinion moves the rack, and the mechanical fixture is such that the plunger of the heparin syringe moves the same distance. The stepper motor is controlled by the 8040 microcontroller located on the Blood Pump Controller board. When the operator enters a desired heparin rate in milliliters per hour (mL/h) via the front panel touch screen, the host 80XX microprocessor converts this information to the appropriate motor step rate and passes it to the Blood Pump microcontroller. The Blood Pump microcontroller outputs a motor step rate logic signal to the Blood Pump Power board where the heparin motor power drive circuitry energizes the appropriate stepper motor coil.

The motor step rate logic signal from the Blood Pump microcontroller is also input to the IO Controller board 8040 microcontroller. The IO microcontroller monitors this signal to determine if the heparin motor is going the appropriate speed. If it determines that an overspeed condition exists, it disables the heparin motor via a disable line that goes to the Blood Pump Power board.

There are two optical sensors to provide information about the state of the heparin pump. The disengage sensor detects when the front panel syringe holder arm is in the disengage position. The end-of-stroke sensor detects when the pinion is raised up on the rack, which occurs when the gear teeth are not meshed. This is an indication of an overpressure condition. The Blood Pump microcontroller monitors the state of these sensors and passes the information to the host 80XX microprocessor.

Level Adjust

The level adjust system allows the operator to change the blood level in the arterial and venous drip chambers. A level up and level down button exists for each drip chamber. The 8040 microcontroller on the Blood Pump Controller board monitors the button positions. When a button is pressed, a valve selects that drip chamber and power is supplied to the motor such that the pump head of a peristaltic pump rotates to apply a positive or negative pressure to the drip chamber. The software logic only accepts one button press at a time. If two buttons are pressed simultaneously, both are ignored.

The motor drive circuitry is located on the Blood Pump Power Board. The motor may be driven in the forward or reverse direction. A direction signal from the Blood Pump Controller Board, along with a pulse width modulated motor rate signal controls two bipolar half bridge motor drivers. Both half bridge motor drivers receive the same motor rate signal, while the motor direction signal is high at one and low at the other to determine the direction the motor runs. The half bridge drivers provide a 24 V pulse width modulated drive voltage of approximately 30 KHz to the motor.

Ambient Temperature Control

The purpose of the cabinet cooling system is to keep the internal temperature of the cabinet lower than the 50°C maximum temperature at which that the electronic components are guaranteed to operate. (Most electronic components are rated to operate at 60°C, the exception is the solid state relay used for heater control.) A fan is located at the base of the cabinet and exhausts the warm cabinet air. An intake vent for the ambient room temperature is located below the CRT on the back of the machine.

The cabinet cooling system consists of the following major components:

Description	Location
Cabinet Fan	Base of cabinet
Blood Pump Temperature IC	Blood Pump Power Bd
Misc IO Temperature IC	Misc IO Electronics Power Bd
Software Fan Control	Host controller
Cabinet Fan Drive	Blood Pump Power Bd

The two LM35DZ temperature ICs are located on the Blood Pump and Misc IO Electronics power boards. This IC outputs a voltage linear with temperature in °C (10.0 mV/°C). These temperature readings are input to the fan control software.

The fan control software always responds to the higher of the two temperatures. Typical values are as follows. At 46°C the fan turns on in the low speed mode and at 48°C it turns on in the high speed mode. There is a 2°C of hysteresis at these threshold temperatures, i.e. the fan returns to low speed at 46°C and turns off at 44°C. In addition, at 60°C a cabinet temperature alarm occurs that results in the machine shutdown state.

The fan power driver is located on the Blood Pump Power board. A motor rate signal from the Blood Pump Controller board determines the duty cycle of a 30 KHz pulse width modulated signal. This signal is input into a passive filter to provide a DC signal to the motor.

UF/Proportioning Control System

The UF/Proportioning Control system monitors and controls the System 1000 dialysate preparation. Six subsystems are controlled or monitored by the UF/Proportioning system. They are:

a. Temperature Control

b. Proportioning Control

c. Flow Control

d. UF Removal Control

e. Conductivity Monitoring

f. Temperature Monitoring

Temperature Control

The UF/PROP system controls the dialysate temperature by enabling a zero voltage crossing solid state relay, which provides the power to a 1500 W heater, with a 5 Hz pulse width modulated digital signal (heater enable signal). The duty cycle of the heater enable signal is updated every 0.5 seconds with the sum of the past duty cycle and a temperature error correction value. The correction value is proportional to the difference between the desired temperature (stored by the host) and the measured control temperature (measured immediately down stream of the heater housing).

The host determined desired temperature is calculated using the user entered desired temperature and the stable "B" conductivity probe temperature. If the stable "B" conductivity probe temperature is different from the user entered desired temperature by more than 0.05°C, then the control temperature threshold sent to the UF/PROP controller is updated so that the "B" conductivity probe temperature will equal the user entered desired temperature. In this way, the dialysate temperature at the "B" conductivity probe will be adjusted so that flow rate and ambient temperature effects on the "B" conductivity probe temperature (and the primary temperature, displayed on the video screen) will be compensated. This control temperature adjustment is performed a maximum of every 5 minutes.

Proportioning Control

The UF/PROP system controls the concentrate(s) to water proportioning ratios by controlling the dialysate flow rate, the "A" concentrate flow rate, and the "B" concentrate flow rate.

The "A" and "B" concentrate pumps are stepper motor driven (each by a cam/follower) diaphragm pumps which deliver a calibrated volume of concentrate per stepper motor revolution. Their flow rates are controlled by controlling the speed of the stepper motors. The concentrate pumps are unidirectional and utilize the proper actuation of a three-way valve for their intake and output pumping strokes. The intake stroke is synchronized by a signal that is generated by an optical interrupter sensor which senses a pin mounted on the cam of the pump assembly.

The UF/PROP controller utilizes the fact that the stepper motors require 200 motor steps per revolution (between each synchronization pulse) to check the concentrate pumps for stepping errors. If late or early synchronization pulses are received then the associated error conditions are reported on the screen during the Technician Mode of the machine.

During the Rinse Mode, the host determines the concentrate treatment mode based on the "A" and "B" rinse port interlock information. If the "B" concentrate line is not on the "B" rinse port, a bicarbonate treatment is initiated by setting the proportioning ratios and the conductivity alarm limits appropriately. Conversely, if the "B" concentrate line is in the "B" rinse port, an acetate treatment is initiated. Using the dialysate flow rate and the proportioning ratios, the host determines the associated concentrate flow rates and stores the two concentrate pump speeds in the UF/PROP controller. The porportioning mode (for acetate or bicarbonate dialysis) cannot be changed in the Prime or Dialyze Modes.

The control of the dialysate flow rate is described in the Flow Control section of the UF/PROP controller description.

Flow Control

The UF/PROP system controls the dialysate flow rate by controlling the time between the switching of the flow equalizer (volumetric pump) valves (provided that all the fluid within the flow equalizer chambers has been exchanged).

The average flow equalizer volume is calibrated (measured) during the Calibration Mode. The time between the switching of the flow equalizer valves is scaled by the host (according to the calibration constant) and stored in the UF/PROP controller so that the user entered desired dialysate flow rate is achieved.

To guarantee the complete fluid transfer to/from the flow equalizer chambers two flow sensors are located within the fluid path to detect the absence of dialysate flow. The time at which both sensors detect no flow has been defined as end-of-stroke. The end-of-stroke time has been defined as the time between moment end-of-stroke was sensed and the desired flow equalizer valve switch time. Since the supply pump speed controls the instantaneous dialysate flow rate, the UF/PROP controller servos the supply pump speed in order to maintain a consistent end-of-stroke time.

Since the flow equalizer volume is calibrated and the end-of-stroke time is controlled, the UF/PROP system can accurately control the dialysate flow rate to the user entered value.

UF Removal Control

The UF/PROP system controls the UF removal rate by controlling the time between the switching of the UF removal metering device valves. The UF/PROP system controls the accumulated UF volume by counting the number of UF removal meter strokes.

Since the UF removal metering device volume is calibrated (measured) in the Calibration Mode, the rate which the host (80XX microprocessor) passes to the UF/PROP controller (number of seconds between valve switches) is scaled so that the user entered UF removal rate is achieved.

In the same way, the user entered UF removal volume is scaled by the UF metering device's stroke volume to a number of UF meter strokes. The host passes the number of UF meter strokes to the UF/PROP controller. The UF/PROP controller will then switch the UF removal meter valves and decrement the stroke number, at the desired rate, as long as the stroke number is greater than zero. The host can then calculate the UF removal volume accumulated by subtracting the number of UF strokes remaining, scaled by the stroke volume, from the operator entered desired UF removal volume. The accumulated volume is displayed during the Dialyze Mode. This value remains during the Rinse Mode and is cleared upon the entry of the Self Test Mode.

In Rinse, the UF removal rate is 3.6 L/h and screen indicates no UF volume accumulated. During the Self Test Mode, no UF removal occurs except for during specific self tests performed by the machine (no UF volume is accumulated). In the Prime Mode, the UF removal rate is set by the operator and is no greater than 0.5 L/h (no UF volume is accumulated). During the Dialyze Mode, the UF removal rate is set by the operator and is limited to be between 0.1 and 4.00 L/h. For UF removal to occur in the Dialyze Mode the following conditions must be met:

1. A target UF volume and a UF rate have been entered (or treatment time and target UF volume have been entered and a machine calculated UF rate is used).

2. The blood pump is pumping.

3. The target UF volume has not been reached.

Conductivity Monitoring

Conductivity is used as a measurement of the electrolyte composition of the dialysate. Conductivity is usually defined as the ability of a solution to pass electrical current. The conductivity of dialysate will vary due to the temperature and the electrolyte composition of the dialysate.

The UF/PROP system measures conductivity at two locations in the flow path using alternating current resistance measurements between each of the conductivity probes' electrode pairs. The two flow path locations are at the "A" conductivity probe and the "B" conductivity probe, which are located immediately down stream of the "A" and "B" mixpoints/ mixchambers, respectively.

One electrode of each of the probes is stimulated with a 1 kHz ac voltage while the other is held at virtual ground (current sense electrode). Two voltages are produced by the resistance measurement circuit. The ratio of the voltages is proportional to the resistance of the respective probe. The resistance of the probes has been modeled as a function of temperature and conductivity. Since each of the conductivity probes contains a thermistor, the temperature at each of the probes is known. Using the model that was derived for the probes, the temperature measured at the probes, and the resistance measured at the probes the conductivity is calculated.

Each conductivity probe is calibrated during the Calibration Mode, at which time the resistance of each probe is measured at a known conductivity and temperature (by the use of an external reference meter) for the scaling of the probe's base resistance in the relationship described previously.

The UF/PROP system generates alarms from the measured conductivities at the "A" and "B" probes. Since these conductivity alarms are used to verify the proportioning ratios, the alarms are generated by testing the "A" conductivity and the "B" portion of the total conductivity ("B" portion = "B" conductivity – "A" conductivity). The alarm limits are determined from the concentrate treatment mode and are stored in the UF/PROP controller by the host. Therefore only during a bicarb treatment would the host store a non-zero expected "B" conductivity portion.

The host determines the concentrate treatment mode during the Rinse Mode by reading the "A" and "B" rinse port interlock information. If the "B" concentrate line is not on the "B" rinse port, a bicarbonate treatment is initiated by setting the proportioning ratios and the conductivity alarm limits appropriately. Conversely, if the "B" concentrate line is in the "B" rinse port, an acetate treatment is initiated. Upon exiting the Rinse Mode the concentrate treatment mode is set for the remainder of the dialysis treatment (concentrate treatment mode is only adjusted in the Rinse Mode).

Temperature Monitoring

The UF/PROP system measures the dialysate temperature at three locations in the fluid path. The first location is directly after the heater and this thermistor, the heater thermistor, is used for the primary temperature control feedback. The next two thermistors are contained in the "A" and "B" conductivity probes. These temperatures are used to temperature compensate the "A" and "B" conductivity measurements. The "B" conductivity temperature is also used to generate a backup high temperature alarm.

The temperature measurement circuit used throughout the machine consists of a voltage divider with a Thevenin Equivalent circuit of 3062 Ω in series with a 7.55 V supply. The voltage divider circuit when connected to the thermistor used in the temperature measurement system referenced to ground produces the voltage to temperature relationship of

$$T \ (°C) = (3.77V - Vtemp) * 12.73 \ (°C/V) + 37°C.$$

The tolerance on the component parameters used in the temperatur measurement system can be as great as 10%, therefore the temperature to voltage relationship must be calibrated. Calibration of the temperature measurements is a two point calibration done at 30 and 40°C. The calibration procedure results in a calibration constant for both the slope and the offset for each temperature probe/circuit.

In the UF/PROP controller the voltage described above as Vtemp is measured for the three temperature probes in its system on a scheduled basis (every 0.2 seconds for the "A" and "B" temperatures and every 1 second for the heater temperature).

The temperature that is displayed on the video screen is measured at the primary ("dialysate") conductivity probe, located just before the bypass valve, by the IO controller.

Miscellaneous Input/Output Control Systems

Nine subsystems are controlled or monitored by the I/O control system. They are:

- Air detector
- Blood leak detector
- Dialysate pressure monitor
- Heparin pump overspeed monitor
- Bypass system and flow sensor
- Conductivity monitor
- Temperature monitor
- Line clamp
- Power fail alarm

Air Detector

The air detector assembly utilizes a set of 2 MHz piezo crystals. One crystal functions as an ultrasonic transmitter and the second crystal functions as a receiver. The emitter and detector are housed into identical assemblies. There is a distance of 0.20 inch between these assemblies into which the venous blood line is placed during dialysis. The emitter is driven by a 2 MHz squarewave that is derived from a crystal oscillator located on the I/O Electrical Power board. When there is fluid in the blood line between the crystal assemblies, the 2 MHz signal is coupled to the detector assembly. The return signal from the detector assembly is amplified and rectified by two independent circuits also located on the I/O Electrical Power board. These dc output levels are monitored using two different methods. The first method is the software generated alarm and the second is the hardware generated alarm.

Software Alarm Detection (Primary Alarm)

One output is fed from the I/O Electrical Power board to an A to D converter and read by the 8040 microcontroller on the I/O Controller board. This value is averaged over a 400 msec time period and reduced by multiplying it by 15/16 and subtracting 50 mV (for noise immunity). This new value is then converted back to an analog level

to be used as an alarm limit. This software generated limit is compared to the rectified dc signal from the detector. The output state of this comparator is monitored by the on-board 8040. When the unaveraged signal falls below the software generated limit for longer than a calibratable time period, an alarm occurs. Sensitivity of the software alarm is 10 microlitres at 300 mL/min blood flow.

Hardware Alarm Detection (Secondary Alarm)

The hardware alarm is redundant to the software generated alarm. This alarm uses two comparators on the I/O Electrical Power board. One comparator looks for a minimum dc level from the rectified detector signal which guarantees the presence of fluid in the venous tubing. The second comparator is ac coupled to react to a large air bubble in the tubing. Sensitivity of this detector is approximately 300 microlitres at 300 mL/min blood flow. Both comparator outputs are wire OR'd together so that either comparator will generate an alarm.

Blood Leak Detector

The detector assembly consists of a high efficiency green LED and a photocell. These components are installed into a housing through which spent dialysate passes. Both of these components connect to the I/O Hydraulic Power board. The LED is connected to a voltage to current converter on the I/O Hydraulic Power board. The input to this circuitry comes from the I/O Controller board. The photocell is tied to the +5 V reference supply through a 750k ohm resistor. This provides a voltage divider which is monitored on the I/O Controller board.

The current through the LED is adjustable and controlled via a D to A output from the I/O Controller board. The light intensity of the LED is adjusted to illuminate the photocell to a point where its resistance is below the alarm threshold. During a blood leak, the presence of blood in the housing attenuates the light striking the photocell which causes an increase in both the photocell resistance and voltage. The increase in voltage (monitored by the microcontroller on the I/O controller board) results in a blood leak alarm.

Dialysate Pressure Monitor

The dialysate pressure is sensed by a resistive bridge pressure transducer located just upstream of the dialyzer. The transducer is connected to a differential amplifier circuit on the IO Hydraulics Power board designed to provide a measurement from −400 to +500 mmHg. The differential amplifier circuit also has an offset input that comes from a software calibratable variable, DAC_OFFSET. The output of the amplifier drives an A/D input channel of the IO Controller system, at which point it is converted to a 10 bit digital value. The calibration of the pressure input is handled entirely in the software, requiring that the design of the amplifier guarantee that the output remains within the A/D input range of 0 to +5 V over the input pressure range and over all component tolerances.

Heparin Pump Overspeed Monitor

To insure that the heparin pump does not exceed its set speed, the IO controller board software monitors a clock signal from the Blood Pump Controller board that is equivalent to 1/4th the heparin pump step rate. In the event that a heparin pump overspeed occurs, the IO

controller board disables the heparin pump via a hardware line that goes to the Blood Pump Power board and notifies the host of the alarm.

To determine if the heparin pump is running the correct speed, the time it takes for ten clock signals to occur is measured (and stored in variable HEPTIMER) and compared against a minimum time period that is set by the host (HP_P_MIN). If the measured period is less than the host set limit, a normal speed alarm occurs. The host is notified of the normal speed alarm and the heparin pump is disabled via the hardware line to the Blood Pump Power board.

When the heparin pump rate changes, the host resets the minimum time period, HP_P_MIN, and the IO controller waits for the first clock signal to restart the timer (this first clock is not counted as one of the ten). In this way, the alarm logic is resynchronized with the heparin pump stepper motor.

The IO controller board also monitors the total amount of heparin delivered in the high speed bolus mode. When it receives clock signals at a rate faster than a predetermined speed, it assumes the pump is operating in the high speed mode. It has a high speed counter, H_SPD_CNTR, that is set by the host. If more high speed counts occur than are in the counter, a high speed alarm occurs. The host is notified of the high speed alarm and the heparin pump is disabled via the hardware line to the Blood Pump Power board.

Bypass System and Flow Sensor

The bypass mode is initiated when a primary dialysate alarm is detected by the IO Controller board, when a redundant dialysate alarm is detected by the UF/PROP Controller board, when the host requests bypass, or when the manual bypass button is pushed.

The bypass valve is in the bypass position when deenergized. It is driven from the nominal +24 V supply with a straight on/off transistor control on the IO Hydraulics Power board.

To verify that there is not a failure in the bypass system, a flow sensor just downstream of the predialyzer bypass valve checks for flow. If flow exists during the bypass mode, a Bypass Fail Alarm is set and the machine is put in the safe, nonfunctional, Shutdown state. If there is no flow when not in the bypass mode, a No Flow alarm is generated.

This flow sensor consists of two thermistors. The first is a reference thermistor used to determine the fluid temperature. The second thermistor uses thermal dilution to sense the fluid flow. The voltage outputs from the thermistors on the IO Hydraulics Power board drive A/D input channels on the IO Controller board where they are converted to 10 bit digital values. A software algorithm in the IO Controller code uses these inputs to determine the flow condition. The design of the voltage divider guarantees that the output remains within the A/D input range of 0 to +5 V over the input temperature/flow range and over all component tolerances.

Conductivity Monitoring

The conductivity probe itself consists of two stainless steel probes inserted into the flowpath just prior to the dialyzer. The drive signal for the conductivity probes is a capacitive coupled squarewave generated on the I/O Hydraulic board. This signal is sent to the conductivity probe and a monitor circuit. Both the monitor circuit and the return signal are rectified and filtered. These dc values are routed to I/O Controller board along with the temperature signal.

On the I/O controller board, the temperature, conductivity, and conductivity reference signals are input to an A to D converter that is monitored by an on board 8040 microcontroller. The microcontroller calculates the temperature compensated conductivity. This value is then displayed on the CRT as the conductivity in milliSiemens.

Temperature Monitoring

The thermistor installed in the conductivity probe changes its' resistance in response to changes in temperature. This conductivity probe is located just prior to the bypass valve and is the final temperature and conductivity measurement point. The values for conductivity and temperature measured at this point are displayed on the CRT and are used to generate the primary alarms for patient safety. If either value is outside of set limits, a bypass condition and audio alarm occur.

The thermistor is wired to a resistor divider network on the I/O hydraulic board. The output of this divider network is sent to the Miscellaneous I/O controller board where it is monitored by the on board 8040 microcontroller via an A to D converter network. From this information, the controller calculates the temperature using offset and gain inrmation stored in the host from the calibration. Calibration of the temperature measurement is a two point calibration done at 30 and 40°C.

Line Clamp

The line clamp opens with a solenoid and clamps with a spring return. When the solenoid is not energized, the spring pushes the plunger away from the solenoid. This causes the plunger to clamp the blood tubing. When the solenoid is energized, it pulls the plunger in with enough force to overcome the spring force. This unclamps the blood tubing. In the event of a power failure, the solenoid is de-energized causing the blood line to be clamped.

The solenoid is controlled by the line clamp board. On the line clamp board is a pulse width modulated current controller. This circuit applies sufficient current to the line clamp solenoid to pull in the plunger. After pull in, the controller ramps the current down to a level capable of holding the line clamp open. This cut back in current reduces the temperature of the solenoid, resulting in a more reliable device. Also located on the line clamp board, is a quick release circuit which helps dissipate the power stored in the solenoid. The result of this circuitry is a quicker and more repeatable clamp time over the life of the machine.

Control for the line clamp comes from the Miscellaneous I/O controller board via the I/O power board. The control signal for clamp

and unclamp is optically coupled on the line clamp board. This provides electrical isolation between the high voltage used to operate the line clamp and the low voltage used for the control signals from the microprocessor.

Power Fail Alarm

The power fail alarm circuitry is located on the Misc I/O Electrical Power board, and includes a CMOS power state flip flop powered by a 1 Farad (F) capacitor. The flip flop, which can be toggled by either the front panel power button or the 80XX system controller, provides the following functions:

- When power is not supplied to the machine (i.e. when the +5 V supply is off) and when the flip flop is in the on state, then power is supplied from the 1 F capacitor to the audio alarm device. When power is supplied to the machine, the flip flop's output state is read by the 80XX, which provides indication of the intended machine power state. Also, when the flip flop is in the on state, power is supplied to the front panel power switch LED.

- The first function listed above results in the power fail alarm. The alarm occurs either if the machine loses power while it is running, or if the front panel power button is pressed "on" when there is no power supplied to the machine. The alarm can be silenced by toggling the flip flop off through pressing "off" the front panel power button.

Power System

The System 1000 power system consists of the following primary components:

- Power line circuit breaker/power switch
- Power transformer input fuse
- Power transformer
- Unregulated +24 V power supply
- +5 V, +12 V and –12 V logic power supplies

All current from the power plug passes through the power line circuit breaker, which doubles as a main power switch. Both sides of the power line are broken by the circuit breaker. Two loads are fed from the breaker, the dialysate heater and the power transformer. Because the transformer draws much less power than the heater, a fuse is in series with its primary, which protects the transformer from a shorted secondary winding.

The transformer has three secondaries: a 20 Vac winding which supplies the +24 V supply, a 120 Vac secondary which supplies the logic power supply, and a 20 Vac winding which supplies the isolated voltage to the RS-232 interface. The +24V supply provides power to the machine's motors and solenoids, as well as to a +12V switcher which powers the CRT display. The logic power supply provides power to all the digital and low power analog circuitry.

M mory Controller Board

The memory controller board is designed to plug into the (IBM XT compatible) motherboard, and provides the following functions:

1. Six 28-pin EPROM sites allowing 384 Kbytes of ROM (read only memory) for program storage.

2. 8K bytes of non-volatile memory (CMOS RAM with self contained battery).

3. Realtime clock module (self contained with battery).

4. Asynchronous serial communications port (requires external isolation buffers, provided on a separate board).

5. External memory card interface (requires separate personality board).

6. 4 position dip switch for machine configuration control.

This board is designed to operate in conjunction with a modified motherboard. The modification involves disabling the motherboard's data buffers above address 256K. The memory controller's ROM space is mapped into the address space from 256K to 640K, with the portion between 256K and 312K being mapped also to address range 832K to 888K. The code at this upper address range is configured as a BIOS extension, which results in the ROM being given control by the motherboard's BIOS software following power on initialization. Unlike the standard BIOS extensions, the System 1000 code does not return to the BIOS after being given control.

Additional features:

A jumper (JP5) provides the capability of selecting an alternate memory configuration (presently disables ROM chip select functions, allowing operation with a floppy disk and second 256K of RAM) for development purposes. During normal operation, the jumper is either removed or placed on pins 2 and 3.

Circuitry is provided to insert memory wait states for any read or write operation of either memory or I/O (except memory refresh operations on the motherboard RAM array). This compensates for the added buffer delays, as well as the slower (than RAM) ROM devices.

Circuitry is also provided to extend the trailing edge of the write strobes (for both memory and I/O) so that the data buffers remain enabled well beyond the end of the PC Bus write strobes.

Programmable array logic (PAL) devices are used for address decoding for both memory and I/O devices.

System Architecture Block Diagram

TEMP CNTL
UF PUMPS
UF VALVES
PROP PUMPS
NP PUMP
COND MEAS
TEMP MEAS

UF/PROP POWER

UF/PROPORTIONING CONTROLLER
– UF SYSTEM CONTROL
– CONCENTRATE PUMP CONTROL
– COND/TEMP MEASUREMENT
– HEATER CONTROL

CRT

DISPLAY DRIVER *

D/A

TOUCH SCREEN INTERFACE

PATIENT BLOOD PRESSURE MONITOR

RS-232

BLOOD LK DET
DIAL PRESS
COND & TEMP
FLOW VALVES
AIR ALARM
LINE CLAMP
SWITCHES
AUDIO ALARM

MISC I/O ELECTRONICS POWER

MISC I/O HYDRAULICS POWER

MISC I/O
– BLD LK/AIR ALARMS
– COND/TEMP MEASURMENT
– DIALISATE PRESS MEASUREMENT
– SYSTEM WATCHDOG
– ON/OFF, BYPASS VALVE DRIVERS
– HEPARIN PUMP OVERSPEED ALARM

I/O CHANNEL
80XX MOTHERBOARD
– 256K RAM
– TOUCH SCREEN INTERFACE

POWER SUPPLY   *
– +5V AT 10A
– +12V AT 1.5A
– –12V AT .5A

+24V PWR
(14A)

SND L/C
BLD PRESSURES
LEVEL ADJUST
HEPARIN PUMP
SEC BLD PMP
PRIM BLD PMP

BLOOD PUMP POWER

BLOOD PUMP CNTL
– BLOOD PUMP SPEED CONTROL
– BLOOD PRESSURE MEASUREMENT
– LEVEL ADJUST CONTROL
– SND CONTROL
– HEPARIN PUMP CONTROL
– AMBIENT TEMP CONTROL

MEMORY/CLOCK
– 384K ROM
– TIME OF DAY CLOCK
– RS-232
– 8K NONVOLATIVE RAM
– 64K MEMORY CARD

RS-232

MEM CARD

Software Flow Charts

DIALYSIS DELIVERY SYSTEM

MAIN POWER ON
do system initialization before starting the main program excution.

BEGIN: (Start Main Program)
Initialize I/O Port System
Initialize Global Variables
Restore Touch Screen Params

Is touch screen present
if not calibrated:
Do screen_calibrate

if TECH_flag:
run Calibrate system
Initialize Graphics Control

Display Startup Messages

If Graphics Error — Yes / No

Start Inter-System Communications
Build Startup Graphics User
Interface System Screen (GUI)
Test for Any Initialization
ERRORS And Display Them
Call: alarm_window_update ()

REPORT STARTUP ABORT ERRORS
abort_program:
Display ERROR Messages
Wait for user touch_input ()
then goto: BEGIN (restart)

If Comm. Error — No / Yes

Main Program Tasks Pg. 2

Soft Power ON/OFF ? — ON / OFF

Wait for power on:
clear HELP/REPORT window.
time_stamp (current time).
turn heater & flow OFF.

POWER ON/OFF — Off / ON

Dialysate Delivery System

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EA 16

(from page 1)

Main Program Tasks

system_activity().
/*
update m activity indicator.
update blink color palettes
*/

data_input().
/*
update local time clock.
input data from controllers.
scale the data.
*/

get_dip_switch_data().
bp_communications().
uf_communications().
io_communications().
port_communications().

limit_pos_test().
/*
update arterial and venous
bargraph limit indicators.
*/

verify_test().
/*
test for HELP/REPORT
ALARM window time out.
display activity indicator
*/

data_output().
/*
output data IO System
BP System, UP System
test and get output for
the NO FLOW and BYPASS
FAIL display logic
*/

gd_schedule().
/*
update GUI display windows
*/

self_test().
/*
do self test as the system
demands
*/

error_test().
/*
display any pending ERROR
messages
*/

test_state().
/*
update alarm logic, test the
state flow and update the
system state machine
*/

notdone + key_functions().
/*
input data from the debug
keyboard or get new position
data from the touch screen
*/

Return (to page 1)

Main Program Tasks

I/O Controller Software

Measure sensor voltages

25ms timer expired ?

yes

Select ADC CHANNEL A-to-D conversion

CHANNEL=0 — yes → Conductivity measure and alarm

no

CHANNEL=2 — yes → Temperature conversion and alarm

no

CHANNEL=4 — yes → Bypass flow sensing

no

CHANNEL=7 — yes → Blood leak alarm

no

CHANNEL=9 — yes → Dialysate pressure conversion and alarm

no

Measure Air Det voltage
Set Air Det threshold
CHANNEL = next CHANNEL

Return

POWER UP

Initialization
RAM test
Clear RAM
ROM test
PSW test
Peripheral chips
Default values
Set Initial State Variables

Measure sensor voltages
Check software and hardware
  air alarm status
Check line clamp status
Check for change in heparin
  pump speed
Check interlock D1 & D2 delay timer
Communicate with host
Refresh analog outputs
Execute state machine
Clear requested alarm bits

FOREGROUND count = 0

no → Increment FOREGROUND

yes

toggle LED indicator
monitor power supply voltages

correct PROGRESS byte pattern ?

no → Shutdown Set NOTIMER bit

yes

PROGRESS = 0
Reinit FOREGROUND

I/O Controller Software
continued

The circles represent I/O controller states that are charaterized by the following parameters:

Shutdown: Machine in bypass, line clamp clamped, bloopd pump disabled, heparin pump disabled

Dialyze: If extracorporeal alarm, controller stops blood pump and clamps line clamp.
If dialysate alarm, controller puts machine in bypass.
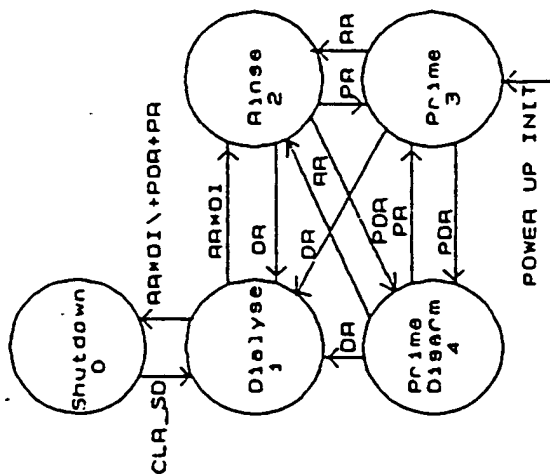If heparin overspeed alarm, controller stops heparin pump.

Prime: If extracorporeal alarm, controller stops blood pump and clamps line clamp.
If dialysate alarm, controller puts machine in bypass.
If heparin overspeed alarm, controller stops heparin pump.

Prime Disarm: If dialysate alarm, puts machine in bypass. If extracorporeal alarm (blood leak and air detector only), no controller response.

Rinse: Controller does *not* take alarm response actions joutlined in Dialyze state.

The lines denot state transitions with the required signal(s) to make the transition noted beside the lines. These control signals are detailed in the Legend.

TIMER INTERRUPT HANDLER

1ms INTERRUPT

Air bubble sampling
Air bubble size measurement
Software Air Detection
Software watchdog
Check Heparin Overspeed Alm Status
Inc 25ms timer

25ms timer is up ? — no / Yes

Inc HEPTIMER, CMDTIMER
Inc BYPASS_SENSE_TIMER, ADC_TIMER
INTERLOCK_DELAY_TIMER

Check connector interlocks

TIMER INTERRUPT RETURN

I/O CONTROLLER STATE MACHINE

Shutdown 0
Dialyse 1
Rinse 2
Prime 3
Prime Disarm 4

RR, PR, DR, RR+DI\+PDR+PR, RR+DI, CLR_SD, PDR, POWER UP INIT

LEGEND:
RR = Rinse Request
DR = Dialyze Request
PR = Prime Request
PDR = Prime Disarm Request
CLR_SD = Clear Shutdown
DI\ = both Dialyzer lines on Rinse fittings

I/O Controller Software page 2

HOST COMMUNICATIONS

Top Level
xx_proc (i.e. BP_proc, UF_proc, or IO_proc)
Called from main() and timer int.

Call converse() to update controller communications

Is an immediate command in process?
— Yes / No

Place next queued command in the immediate command buffer.

Check for requested communications from host (via xdat array). Queue up resulting commands in qdat array.

Check for data received from controller (via iqdat array). Process new data.

Check for new status received from controller. Process any change in status.

Process controller specific logic.

Return to main

Middle Level
(Converse)
Called from xx_proc and timer interrupt.

Call uccom() for low level communications (see page 2)

Current command complete?
— No / Yes

Time for status request?
— Yes → Start status request
— No

Immediate command ready?
— Yes → Start immediate command
— No

Start next command in the circular command queue

Return

Host Communications
continued

(Transmit mode)

A → Echo received from uController

Yes → Echo value correct?

Yes → End of current command?

Yes → uC response required?

Yes → Set status to receive mode.

No (from Echo received) →

No (from Echo value correct?) → Report error code

No (from End of current command?) → Output next byte to uC port.

No (from uC response required?) →

Return to XX_proc

Low Level (Uccom) Called from XX_proc()

→ Is command ready or in process?

Yes → Beginning of new command?

No →

Yes → Output command to uC port.

No (Beginning of new command?) → Communication mode?

Transmit (default) → A

Receive → New data received?

Yes → Echo data to uC

No (New data received?) →

All expected data received?

Yes → Set status to transmit mode.

No (All expected data received?) →

Host Software page 2

BLOOD PUMP CONTROLLER
SOFTWARE FLOWCHART 8/1/90

INIT

INIT →

INITIALIZE IO & COMMUNICATION PORTS →

TEST RAM AND ROM →

RAM OR ROM ERROR?
— NO →
— YES →

SEND ERROR FLAG TO HOST →

INITIALIZE RAM, TIMER, & COMMUNICATIONS →

ENABLE INTERRUPTS

INTER

(A) →

TURN ON LEV ADJ MOTOR & SELECT APPROPRIATE VALVE →

IN SHUTDOWN?
— YES →
— NO → (B)

CLEAR ALL D/A VALUES →

OUTPUT D/A VALUES
BLD PMP MTR1
BLD PMP MTR2
LEV ADJ MTR
CAB FAN MTR →

1600 LOOPS SINCE LAST CHECKED SCHEDULED EVENTS?
— YES →
— NO →

HAVE ALL SCHEDULED EVENTS OCCURRED?
— NO →
— YES →

CALL SHUTDOWN →

MAIN

MAIN

MAIN →

COMMUNICATE WITH HOST →

DO BLD PMP MOTOR CONTROL (CALL MOTOR1) →

DO HEPARIN PUMP CONTROL →

100msec SINCE LAST READ A/D VALUES?
— NO →
— YES →

READ & STORE
VENEOUS PRESS
ARTERIAL PRESS
SND PRESS
AMBIENT TEMP
D/A REF VOLT
5V SUPPLY
12V SUPPLY →

DO CABINET FAN CONTROL →

DO BLD PMP EMF ERROR CHECK (CALL CHK_MTR) →

IS A LEVEL ADJUST SWITCH ON?
— NO → (B)
— YES → (A)

EA 22

Blood Pump Controller Software
continued

BLD PMP EMF ERROR CHK

IS MOTOR OFF FOR EMF TEST & IS IT TIME TO TURN ON? — YES / NO

.5 SEC SINCE LAST EMF TEST? — YES / NO

IS MOTOR ON AND DOOR SHUT? — YES / NO

DOES TACH COUNT VERIFY MOTOR IS RUNNING? — YES / NO

SEND ERROR MESSAGE TO HOST

IS EMF TEST DELAYED? — YES / NO

TURN MOTOR OFF FOR EMF TEST

WAS EMF LIMIT EXCEEDED 2 CONSECUTIVE TIMES? — YES / NO

COMMAND MOTOR OFF & SEND MESSAGE TO HOST

IS EMF TEST DELAYED? — YES / NO

DOES EMF VERIFY MOTOR IS OFF? — YES / NO

CALL SHUTDOWN

RET

(A) MOTOR SPEED TOO SLOW? (CHECKED EVERY 2 SEC) — YES / NO

SEND ERROR TO HOST

BLD PMP CONTROL

.5 SEC SINCE LAST CONTROL UPDATE? — YES / NO

IS MOTOR COMMANDED ON & DOOR CLOSED? — YES / NO

HAS MOTOR SPEED CHANGED BY > 26 RPM? — YES / NO

SET FLAG TO DELAY EMF MOTOR TEST

DID MOTOR JUST TURN ON? — YES / NO

TURN MOTOR ON & DELAY MOTOR EMF TEST

DO SPEED CORRECTION

MOTOR TOO FAST 2 CONSECUTIVE CHECKS OF TACH COUNT? — YES / NO

CALL SHUTDOWN

RET

(A)

EA 23

Blood Pump Controller Software
continued

EXTERNAL MOTOR INTERRUPT

```
                    NO                          NO
          ┌──────────────┐              ┌──────────────┐
          │              │              │              │
      ◇ BLD PMP          │          ◇ BLD PMP          │
   MOTOR1 TACH           │       MOTOR2 TACH           │
   INTERRUPT? ◇          │       INTERRUPT? ◇          │
          │              │              │              │
         YES             │             YES             │
          │              │              │              │
   ┌──────────────┐      │       ┌──────────────┐      │
   │  INCREMENT    │     │       │  INCREMENT    │     │
   │ MOTOR1 DYNAMIC│─────┘       │ MOTOR2 DYNAMIC│─────┘
   │  TACH COUNT   │             │  TACH COUNT   │──── ( RET )
   └──────────────┘             └──────────────┘
```

4 MSEC TIMER INTERRUPT

```
┌──────────────┐
│ CHECK IF NEED │
│   TO STEP     │
│ HEPARIN MOTOR │
└──────────────┘
       │
       │         NO                    NO                    NO
       │   ┌──────────┐          ┌──────────┐          ┌──────────┐
    ◇ 20 msec         │       ◇ 100 msec        │      ◇ 0.5 sec         │
   INTERVAL? ◇        │      INTERVAL? ◇        │     INTERVAL? ◇        │
       │              │           │             │          │             │
      YES             │          YES            │         YES            │
       │              │           │             │          │             │
┌──────────────┐      │    ┌──────────────┐     │   ┌──────────────┐     │
│ OUTPUT LEVEL │      │    │   UPDATE      │     │   │ SAVE MOTOR 1 & 2│   │
│ ADJUST CONTROL│─────┤    │  FOREGROUND   │─────┤   │ DYNAMIC TACH CNTS│──┤
│    BITS      │      │    │   TIMERS      │     │   │  & REINIT THEM  │   │
└──────────────┘      │    └──────────────┘     │   └──────────────┘     │
                                                              │
                                                           ( RET )
```

EA 24

UF Controller Foreground
(Main Loop)

Start of Foreground Loop

Output the next D/A Channel to be Converted

Communicate with Host

Every 0.2 second measure D/A Ref, A condo, B condo, C condo, Condo Reference, A temperature, and B temperature

Every 1 second measure Heater Temperature, C Temperature, EOS 1 and 2 voltages, 5V Supply, and the +/-12V divider voltage

If either End of Stroke Signal is sensed then set Appropriate End of Stroke Flag

Calculate the A and B Conductivities every 0.4 seconds

If End of Stroke then Calculate and Store the new Supply Pump Voltage

Calculate and store new Heater Duty Cycle every 0.2 seconds

Determine if there is a Conductivity or Temperature Alarm every 0.4 seconds

If Alarm AND Not in RINSE

— TRUE → Activate Bypass

— FALSE → Deactivate Bypass

If Flow Rate has Changed

— TRUE → Calculate and Store new Supply Pump Voltage and Heater Duty Cycle

— FALSE

Update the Diel Pres Relief Valves commanded by the Host every 1 second

If in Calibrate Mode

— TRUE → Enable Concentrate Pumps According to the Associated Host Controlled Pump Calibration Counter

— FALSE

Enable Concentrate Pumps According to the Host Controlled Enable Byte

If All Time Scheduled Routines have not Executed Every 1280 Main Loops Set Error Flag

Jump to Start

UF Controller Foreground (Main Loop)

UF Controller
(Background and Initialization)

If 400msec Interval
- FALSE
- TRUE → Switch the UF Removal Device's Valves if time according to the UF Removal Counter → Set flags for the 0.4 second Tasks

If 1.0sec Interval
- FALSE → Return
- TRUE → Set flags for the 1.0 second Tasks

Initialization Section → Test RAM and ROM

If RAM or ROM Failure
- FALSE → Initialize Hardware → Initialize RAM → Jump to Start
- TRUE → Output Error Code Flash LED Fast Trap Execution

80 usec Timer Interrupt

If 2msec Interval
- FALSE → Return
- TRUE → Step the A, B, and C Concentrate Pumps if time according to the Conc Pump Counters

If 10msec Interval
- FALSE → Return
- TRUE → Switch the Flow Equalizer valves if time according to the Flow Equalizer Counter → Turn off Heater if time according to the Heater Counter

If 200msec Interval
- FALSE → Return
- TRUE → Turn on Heater if the desired Heater Duty Cycle > 0 → Set flags for the 0.2 second Tasks

UF Contoller Background and Initialization

Calibration Mode Flow Chart

```
                          ┌─────────────────────────────┐
                          │  Read input from the        │
                          │  touchscreen and respond     │
                          │  with new value in the       │
                          │  calculator or other screen  │
                          │  changes                     │
                          └─────────────────────────────┘
                                      │
                                      ▼
                              ╱──────────────╲
                             ╱  If EXIT        ╲
                            ╱   Button has       ╲
                            ╲   been pressed     ╱
                             ╲                  ╱
                              ╲──────────────╱
                         TRUE   │        │   FALSE
                                ▼        ▼
                          ╭──────────╮
                          │  Return  │
                          ╰──────────╯
```

Execute the logic required for the enabled UF system calibrations

Execute the logic required for the enabled IO system calibrations

Execute the logic required for the enabled BP system calibrations

Execute the logic required for the enabled system settings calibrations

Print the System Temperature or Pressures on the screen

Communicate with all three Controllers on a routine basis

Program Start

Init the UF, IO, and BP Controllers for calibration

Init the IO_PORT for Calibration

Init the Date and Value Tables for the display of the date or the setting of each calibration on the screen

Print the Calculator and the calibration status on the screen

Calibration Mode Flow Chart

Sample Device Calibration Logic

Sample Device Calibration Logic

Plan

Development Process

The development of the System 1000 hardware/software control system has directly involved a team including degreed electrical engineers with design experience in both hardware and software, and some with over eight years of experience in the dialysis industry. The design effort has consisted of the following four parallel efforts:

1. Main Controller/User Interface hardware/software design
2. Blood Pump System hardware/software design
3. UF/Proportioning System hardware/software design
4. Misc I/O System hardware/software design

The main controller design is based on an IBM PC/AT compatible architecture using an 80XX microprocessor, allowing the use of proven and readily available development tools. The main control software was written in the C language, using the Borland Turbo C revision 2.0 compiler. The compiler's extensive code checking facilities were utilized during the development to reduce the occurrance of coding errors.

The other three systems are each centered around an 8040 (8048 family) microcontroller, with software written in 8040 assembly language. The 8040 microcontroller systems communicate with the 80XX via the PC bus and are capable of functioning and being tested by themselves, independent of the rest of the machine. This allowed them to be developed and tested with a standard personal computer (PC), with relatively simple PC test software.

The system design has been guided by a top level machine specification, which specifies machine features (e.g. programmable sodium, UF control, and cleanable surfaces) and operational requirements (e.g. dialysate flow rate range, input voltage range, and heparin pump syringe sizes). Interpretation of these requirements at the detailed level has evolved as the design progressed. Prior to any detailed design, an initial plan was made which specified the general control architecture, with machine functions being divided among the three 8040 controller systems.

On a biweekly interval, the design team has met to discuss progress and design issues. This format has not only served as a reporting function, but also as a peer review of design issues. In addition, prototype and final design reviews have been held for each circuit board. The 8040 microcontroller code has been reviewed by a team member unfamiliar with the associated design details, providing input on code structure and clarity.

As the user interface was being developed several experienced dialysis nurses provided input on the user interface, identifying potential operator problems and safety concerns.

Prior to the first clinical monitoring machine being installed, extensive validation testing was done to each subsystem, with formal test reports being written to document the results. In addition a validation test protocol was written, consisting of 994 test items,

which verifies virtually every operational feature in every machine state. An experienced dialysis nurse spend several weeks with the machine, validating and manupulating the user interface and identifying potential operation problems and safety concerns. As a final verification, the machine was subjected to six simulated dialysis treatments, with the requirement that no operational problems occur. The treatment conditions were all preplanned, guaranteeing that a wide diversity of conditions were tested.

Monitoring machines are operating in three clinical sites and has sucessfully performed more than 410 treatments as of January 7, 1991. The studies will continue in these and additional clinical locations.

Software Specifications

Overview

The purpose of this specification is to describe the process requirements in the development of the System 1000 Software Control System. This document specifies the general software strategy, the operating system and the programming languages used.

Requirements

Safety

Tests will be done at system power up time and before each patient treatment on hardware devices and the system memory (programmed read-only-memory, ROM, and random-access-memory, RAM).

A software 'watchdog' timer will be utilized to ensure that the background tasks and all critical foreground tasks are active. If any of these monitored tasks become inactive, the machine should revert to a safe state and alert the operator.

User I/O Interface

The display portion of the human interface will be compatible with EGA/VGA graphic interface hardware. In addition, the display messages will be selectable for human language differences (i.e., English, French, German, Italian; and at a future time include Japanese, and possible other symbolic or iconic languages).

Interprocessor Communication

The communications used within the hardware system will be via the system bus. This hardware system typically would include various microcontroller driven peripheral interface devices for the control of: the blood pumps; a heparin pump; valve actuators; etc. Within the scope of this confidence level, the communications between both the main system and the microcontrollers must be verified using redundant acknowledgements. If a communication response is not received by either system within a predetermined time, a machine failure is assumed and a safety shutdown will be initiated.

Remote Computer Communicati n

A serial interface will be provided for remote query of the system by a PC-type computer using a customized interface program.

Module Head r Information

The following information is to be included in an abstract portion of the header information of each software partition or software sub-system.

- Each software partition or sub-system must describe in general the module's purpose and highlight any specific input or output requirements.

- A complete revision history of each partition or sub- system must be included along with the date and a description of the changes. Also, all versions of host system software that the module is compatible with will be listed.

- A description of the programming language used for the partition or sub-system if it differs from the native language used for programming the system.

Control Architecture

In general, the basic context of the operating system is described as a polled system with interrupt driven background events occurring randomly.

The foreground activity is the polled portion of the operating system. During the foreground execution time, various sub-routines or functions are called to gather and input data into temporary storage memory; scale, compute and evaluate limit violations, and set appropriate alarm flags; evaluate state machine flow path data and update the execution of the state machine; output current data to the various hardware sub-systems; update the current data for the graphics display system; and test the system and reactivate the watchdog timer.

In the background portion of the operating system the micro-controller based peripheral interface hardware communications will take place, as well as all interrupt driven devices and activities. Also, the interrupt processing software must provide a means to test the reactivated watchdog timer.

Regardless of the foreground or background activity, the operating system generally must feature safety and reliability, and detected errors must be safely dealt with.

Programming Languages

The programming language of choice for the development of the various partitions and sub-systems of the System 1000 Software Control System are versions of the popular 'C' language. Specifically, Borland International Turbo C Version 2.0 (an ANSI version of 'C') and the Borland International Macro Assembler Version 1.0.

The 'C' language version chosen follows the traditional reference for 'C', the book 'The C Programming Language', by Brian W. Kernighan and Dennis M. Ritchie (which will be referred to as "K&R" from now on). A more complete reference to the 'C' language is the ANSI extensions, ANSI Subcommittee X3J11 (i.e., ANSI 3.7. & ANSI 3.8.)

The following conventions will be adhered to:

- ANSI constructs will be used as the programming guideline.

- The interface meth ds that are used between languages must be indicated (i.e., stack passing, file control block (FCB) or parameter block, etc.).

- Any compatibility problems must be indicated and the solution used to resolve the incompatibility.

- If a special software is used, a description of the programming language used (with appropriate warnings) for the implementation of the partition or sub-system must be provided. Also, the version number of the special software must be listed in the modules written using it.

- If a purchased library is used in any program module, the version number of the purchased library must be listed. Also, a description of the functions used and any special considerations taken in implementation must be provided.

Programming Conventions

The following conventions for program entities, such as: local or global variables, local or global constants, and local or global storage arrays functions and etc., are to be used as the preferred guidelines for module interface within the System 1000 Software Control System or operating system.

Defines

All pre-defined constants, whether local or global, used within a module are to be upper case letters. The use of underscore and numerals is acceptable only if not used for the first character position of the defined name.

Variables

All local variables used within a module are to be lower case letters. The use of underscore and numerals is acceptable only if not used for the first character position of the local variable name.

Generally, all global variables used by any module are to have the first character of the name in an upper case letter, the use of underscore and numerals is acceptable only if not used for the first character position of the global variable name.

Macros

All macros are to be upper case letters, the use of underscore and numerals is acceptable only if not used for the first character position of the defined macro. To ensure the integrity of the macro with respect to the order of precedence of its operations, any parameters used in the macro should be enclosed in parenthesis.

The following is an example:

#define MACRO_A(x) (((x) == ON) ? 1 : 0)

Structures

Structure tag names should be used whenever a structure is defined more than once, with the actual structure definition only existing in

one place. The structure tag name should consist of lower case letters.

The structure name should follow the same convention previously described for variables.

Elements used within a structure are to be lower case letters, the use of underscore and numerals is acceptable only if not used for the first character position of the element.

Functions

All function names used in a module can be either upper or lower case letters, the use of underscore and numerals is acceptable only if not used for the first character position of the function name.

Security Features

- The machine calibrations cannot be modified without the use of a tool. A tool for this purpose can be a specially coded memory card that is plugged into the machine, or a literal tool required to open the cabinet to gain access to a calibration switch.

- The host software will verify, at power on time, that the expected three versions of controller software are present in the three slave controllers.

Miscellaneous Programming Requirements

File Access Functions

No file access library routines should be included in the software [e.g. fopen()]. If file access functions are included for test purposes, they should be conditionally compiled when the constant ROMMABLE has a value of 0.

Structure and Constant Initialization

Structures and constants used by multiple modules should not be defined more than once.

Memory Usage

Large allocations of DATA memory through the declarations of arrays is discouraged. This includes allocating the arrays that are either global or static. The preferred alternative is allocating them on the heap using malloc(). If global access is required to the array, then a global pointer can be declared which points to the memory. In the large memory model the DATA memory is limited to 64K, much of which is used for string declarations.

Prohibited Functions

The following functions cannot be used, because they don't function properly in ROM:

delay()	textbackground()	textmode()
clrscr()	textcolor()	sleep()
bioscom()		

Compiler Checking

All compiler warnings should be recognized and explained.

Prototypes for all functions must exist.

Compiler opti ns settings

Large memory model

C calling convention

Floating point emulation

Default character type: signed

Byte alignment

Underbars generated

Duplicate strings merged

Standard stack frame

Stack overflow tested

Optimized for size

Register variables used

Register optimization used

Jump optimization used

Nested comments off

ANSI keywords only off

Enabled Portability Warnings

- Non-portable pointer conversion
- Non-portable pointer assignment
- Non-portable pointer comparison
- Constant out of range in comparison
- Conversion may lose significant digits
- Mixing pointers to signed and unsigned char

Enabled ANSI Violations Warnings

- 'ident' not part of structure
- Zero length structure
- Void functions may not return a value
- Both return and return of a value used
- Suspicious pointer conversion
- Undefined structure 'ident'
- Redefinition of 'ident' is not identical
- Hexadecimal or octal constant too large

Enabled Common Warnings

- Unreachable code
- Code has no effect
- Possible use of 'ident' before definition
- 'ident' is assigned a value which is never used

- Parameter 'ident' is never used
- Possibly incorrect assignment

Enabled Uncommon Warnings

- Superfluous & with function or array
- 'ident' declared but never used
- Ambiguous operators need parentheses
- Structure passed by value
- No declaration for function 'ident'
- Call to function with no prototype

Linker Options

Segments initialized

Stack warning

Case-sensitive link off (the linking process used to generate the EPROM code version does not function properly if case sensitive linking is used.)

Software Sub-system

Description

Each partition or sub-system must include the following as part of its header information:

- an identification banner must appear as part of the header
- the project name
- a module name or number
- a version number
- an origin date
- a revision date
- the author's name
- the company name and/or division
- the company address
- a copyright date or dates
- the usage violation and restriction information

The following is an example of the header block that will appear at the top of each software partition or sub-system.

```
* .................................................................. *
*                                                                    *
*    Project Name : System 1000                                      *
*                                                                    *
*    Module Name  :                                                  *
*                                                                    *
*    Version #   :                                                   *
*                                                                    *
*    Origin Date  :                                                  *
*                                                                    *
*    Revision Dat :                                                  *
*                                                                    *
*     Author Nam  :                                                  *
* .................................................................. *
*    Company      : Althin CD Medical, Inc.                          *
```

```
          Address   :  13520 S.E. Pheasant Ct.

                    Milwaukie, OR 97222
          Copyright (1988 - 1990) All Rights R  served

          Any use  f this program   ther than for the specific
          purpose   f controlling System 1000 dialysis equipment or
          associated peripheral equipment is strictly prohibited.
 r
      Purpose :
 */
```

In addition, a revision history block containing the following
information will appear directly after the header information in each
software partition or sub- system.

```
 ...........................................................................
 .                                                                         .
 .                                                                         .
 .                          Revision History                              .
 .                                                                         .
 ...........................................................................
 r
 Date   Author        Description
 */
```

Criticality

General Description

Patient safety has been a primary consideration since the conception of the System 1000. The absence of patient hazards as a result of single component failures has been a design rule. In addition, the Self Test Mode has been implemented which ensures that redundant safety mechanisms are fully functional prior to each treatment. The self testing is also used to test non safety related functions to reduce the chances that a nuisance failure is uncovered during a dialysis treatment.

The following lists some of the major design contributions to the machine's safety.

1. Redundant conductivity alarms, with redundant conductivity probes

2. Redundant temperature alarms, with redundant probes

3. Redundant air detector systems

4. Self test verification of venous pressure measurement accuracy using the arterial pressure measurement as reference.

5. Self test verification of the volumetric UF system

6. Three independent A/D measuring systems whose accuracies are compared during selftest.

7. Continuous monitoring of the power supply voltages.

8. Continuous monitoring of the internal ambient temperature.

9. Use of a hardware shutdown line which forces the machine into a safe, nonfunctional condition. All four microprocessors and a hardware watchdog circuit can activate this line.

10. Interlock switches on the dialysate and concentrate line rinse fittings allow the machine logic to prevent inappropriate state changes.

11. Bypass fail detection.

Fault Tree Analysis

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System 1000 Fault Tree Analysis

```
                        1. Patient Injury
                           or Death
                              |
        ┌────────┬────────┬───┴────┬────────┬────────┐
        |        |        |        |        |        |
    2. Severe  3. Infection  5. Hemolysis  6. Electrolyte  8. Air Embolism  9. Overfiltration
    Loss of    or Pyrogen                  Imbalance
    Blood      Reaction
        |        |                            |              |              |
  11. Mechanical  4. Electrical           7. Fire                        10. Underfiltration
     Injury       Shock
```

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System 1000 Fault Tree Analysis

Pump Stops or Fails to deliver enough heparin

Excessive Pressure

End of Stroke

End of Stroke Alarm Fails

Inadequate Heparin Delivery

Clotting Times not Verified

Blood Pump Stop Alarm Failure

Electronic Failure

Open Blood Pump Cover Switch

Operator Error

Improper Heparinization

Line Clamp Interlock Failure

Blood Pump Stops

Operator Ignores Alarm

Blood Pump Fails

No Blood Flow

Blood Clotting

2. Severe Loss of Blood

Blood Leak

Blood Line Blood Loss

Defective Blood Line

Disconnected Venous Needle or Blood Line

Cut venous line

No Low Venous Alarm

Improper Venous X-ducer reading

Pressure Monitoring Circuit Error

• Transducer Protector Wetor Clogged

• Electronic Failure

• Miscalibration

• Defective Transducer

• Defective Venous Monitor

• Alarm Limits Not Set

• Venous Low Alarm Set Below 10 mmHg

Dialyzer Blood Loss

Blood Detector Does not sense Blood

• Electronic Failure

• Miscalibration

Massive Dialyzer Blood Leak

Corporeal Blood Loss

Over Infusion of heparin

• Overspeed Alarm Failure

• Heparin Pump Overspeed

Internal Bleeding or Post Surgical Patient

• This state is not allowed
• Function tested prior to each treatment.

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System 1000 Fault Tree Analysis

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System 1000 Fault Tree Analysis

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System 1000 Fault Tree Analysis

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System 1000 Fault Tree Analysis

Fault tree diagram. Top block: **6. Electrolyte Imbalance** feeding through an OR gate to three branches:

- **Procedural Error Technician** (AND gate) → **Monitor Fails to Detect Conductivity Problem** (OR gate) → **Conductivity Alarm Limits not Set Properly** and **Improper Calibration of Conductivity Reading** (AND gate) → **Operator Verifies Improper Conductivity** and **Calibration Failure**.
- **Procedural Error Operator** (OR gate) → **Variable Na or NaHCO3 Setting Error**.
- **Machine Failure (Cond Related)** (AND gate) → **Incorrect Dialysate Composition** and **Conductivity Monitor Failure**.
  - **Incorrect Dialysate Composition** (OR gate) → **Improper Concentrates** (OR gate) → **Improper Concentrate Additives**, **Improper Bicarbonate Concentrate**, **Improper Composition From Manufacturer**; and **Proportioning Error**.
  - **Conductivity Monitor Failure** (OR gate) → **Conductivity Alarm Failure** (AND gate) → **Primary Alarm Failure**, **Secondary Alarm Failure**; **Undetected Bypass Valve Failure** (AND gate) → **Bypass Valve Failure**, **Bypass Monitoring Circuit Fails**; **Improper Calibration of Conductivity Reading** (AND gate) → **Operator Verifies Improper Conductivity**, **Calibration Failure**.

* Function tested prior to each treatment.

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System 1000 Fault Tree Analysis

8. Air Embolism

Machine Related

Non Machine Related

Not Detected Detector Armed

♦ Not Detected Detector Disarmed

Primary Air Alarm Failure

Redundant Air Alarm Failure

Air in the Blood Line

• Blood Pump Stop Failure

• Primary Detector Circuit Failure

• Line Clamp Failure

• Secondary Air Detector Circuit Failure

In Prime Mode

Audio and Visual Cue not Needed

Operator Error (Try to Run Patient in Prime Mode)

Less Than 5 Minutes (Disarm Allowed for 5 Minutes in Prime)

Air in the Blood Line

Unintentional Disarm

Intentional Disarm

♦ Air Detector cannot be disarmed in the Dialyze mode
• Function tested prior to each treatment.

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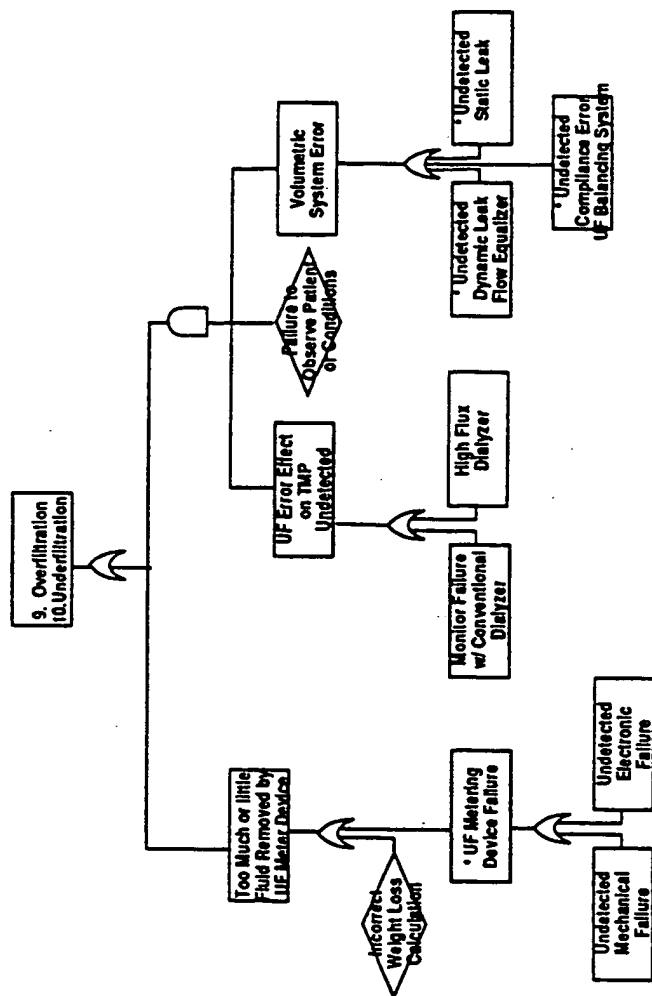
System 1000 Fault Tree Analysis

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System 1000 Fault Tree Analysis
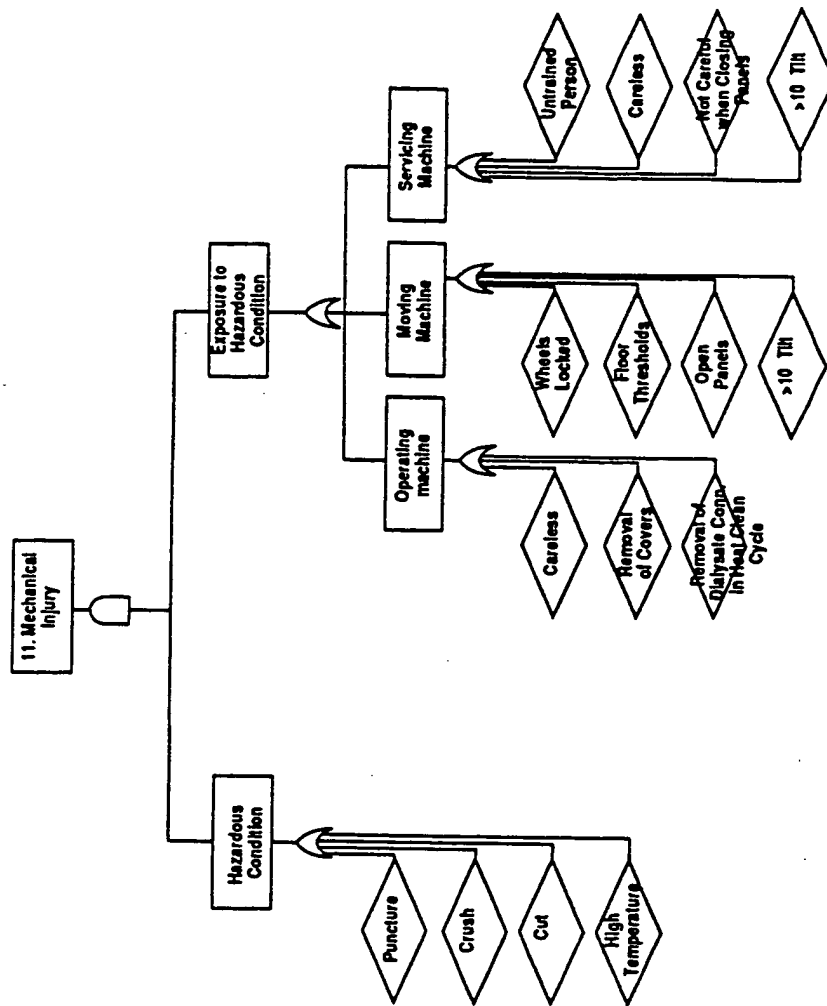
Safety System

The following report is a detailed description of the System 1000 safety systems. Included in the description for each system are its basic function, the components that make up the system, and a discussion of the safety aspects of the system.

A total of fourteen safety systems are defined as follows.

1.	Temperature	8.	Touch Screen
2.	Conductivity	9.	Nonvolatile Memory
3.	Venous Pressure	10.	RS-232 Interface
4.	Air Detector	11.	UF Protective System
5.	Blood Leak Detector	12.	Programmable Sodium
6.	Main Controller (80XX)	13.	Programmable UF
7.	Power Supply	14.	External Memory Card

Temperature

Function

Controls the dialysate temperature to a user set level (from 35 to 39°C), and provides an independent temperature monitoring system which alarms at technician set limits. The alarm response includes halting the flow of dialysate through the dialyzer.

Safety Requirements

A dialysate temperature protective system (which is independent of any control system) prevents dialysate with a temperature greater than 41°C from reaching the dialyzer and activates audible and visual alarms. This system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient.

System Components

- Temperature Controller
- Dialysate Heater
  - Temperature control thermistor located just downstream of the heater (T1)
  - Temperature monitor thermistor located in the second ("B") conductivity probe (T2)
  - The UF/Proportioning uC (microcontroller) controls the power (via duty cycle) to the heater based on T1 and T2 measurements. The T2 measurement is used for a fine adjustment, with a limited correction ability of ±2.8°C. The 80XX uP (microprocessor) provides temperature control information for the UF/Prop uC.
- Primary Temperature Monitor
  - Temperature monitor thermistor in the final ("dialysate") conductivity probe (T3).

- The 80XX uP provides technician adjustable high and low alarm limits to the Misc I/O uC.
- The Misc I/O uC monitors T3 for a temperature outside of technician adjustable limits (upper limit is 41°C maximum).
- The Misc I/O uC directly deactivates the bypass valve (removing flow to the dialyzer) during a primary temperature alarm.
- The Misc I/O uC indirectly (via the 80XX uP) triggers audible and visual alarms.

- Backup Temperature Monitor
  - Temperature monitor thermistor in the "B" conductivity probe (T2)
  - The UF/Prop uC monitors T2 for a temperature greater than 41°C.
  - The UF/Prop uC directly deactivates the bypass valve (removing flow to the dialyzer) during a backup temperature alarm.
  - The UF/Prop uC indirectly (via the 80XX uP) triggers audible and visual alarms.
  - The 80XX uP provides T2 temperature calibration information to the UF/Prop uC.

- Bypass Valve Fail Detection
  - The Misc I/O uC monitors the flow state through the dialyzer using a thermistor based flow detector. This information is displayed on the video screen for operator verification.
  - The 80XX uP verifies the flow state information from the Misc I/O uC for consistency with the intended state of the bypass valve.
  - If flow exists during an intended bypass condition, then the system shutdown line is activated, which halts dialysate and blood flow.

Safety Discussion

Since the UF/Prop uC is responsible for controlling the temperature, the Misc I/O uC provides an independent safety system. The safety system contains three major components who's functions must be verified at the beginning of each treatment. These are:

1. The Misc I/O uC's ability to measure the dialysate temperature using the primary conductivity probe thermistor (T3)

2. The Misc uC's ability to alarm off of a temperature outside of the 80XX uP supplied alarm limits

3. The Misc uC's ability to deactivate the bypass valve

The following tests are therefore performed during Self Test.

1. T3 measurement accuracy test - The 80XX uP compares the Misc I/O uC's T3 measurement with the UF/Prop uC's

measurement of the T2 temperature and verifies that they are within 1°C of each other. In addition, the T3 temperature is continuously displayed on the front panel, allowing user verification of its accuracy.

2. **Misc I/O alarm test** - The 80XX uP consecutively generates both primary temperature alarms by first setting the upper alarm limit to a value below the current temperature, and then by setting the lower alarm limit to a value above the current temperature. An upper alarm is also generated through hardware by shunting the thermistor (T3) with a resistance. In each case, a reported alarm condition from the Misc I/O uC is verified by the 80XX uP.

The following additional test is also performed during the pretreatment testing to guarantee a fully functional system.

3. **UF/Prop alarm test** - Similar to the Misc I/O alarm test described in item #2 above, the backup high temperature alarm in the UF/Prop uC is tested by moving the alarm limit so that it forces an alarm conditions. The alarm response is then verified.

Conductivity

Function

Controls the concentrate proportioning ratio to a user set level, and provides an independent conductivity monitoring system which alarms at a maximum deviation of ±5% of the desired conductivity. The alarm response includes halting the flow of dialysate through the dialyzer.

Safety Requirements

A dialysate concentrate protective system (which is independent of any control system) prevents dialysate with a concentration deviation greater than ±5% of the desired concentration from reaching the dialyzer, and activates audible and visual alarms. This system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient.

System Components

- Concentration Control
    - Stepper motor driven volumetric concentrate pump(s)
    - The UF/Prop uC controls the speed of the concentrate pump (s).
    - The 80XX uP provides concentrate pump speed information to the UF/Prop uC based on the desired concentration information entered by the user, the dialysate flow rate, and on the concentrate pump calibration.
- Primary Conductivity Monitor
    - Final (patient) conductivity probe just upstream of the bypass valve (C3)

- The Misc I/O uC calculates the primary conductivity limits at ±5% of the measured conductivity after user verification that the conductivity is acceptable.

- The 80XX uP verifies that the ±5% conductivity limit calculation is correct.

- The Misc I/O uC monitors C3 for a conductivity outside of the alarm limits.

- The Misc I/O uC directly deactivates the bypass valve (removing flow through the dialyzer) during a primary conductivity alarm.

- The Misc I/O uC indirectly (via the 80XX uP) triggers an audible and visual alarm.

- Backup Conductivity Alarm

  - The primary conductivity measurement, provided to the 80XX uP by the Misc I/O uC.

  - The 80XX uP monitors this measurement for a conductivity outside of technician settable limits.

  - The lower limit can be set within a range of 9 to 14 mS/cm.

  - The upper limit can be set within a range of 13 to 19 mS/cm.

  - The 80XX uP deactivates the bypass valve (via the Misc I/O uC) during a backup conductivity alarm condition.

  - The 80XX uP activates an audible and visual alarm.

- Redundant Conductivity Monitor

  - The conductivity probe just downstream of the "B" mix point (C2)

  - The conductivity probe just downstream of the "A" mix point (C1)

  - The 80XX uP provides conductivity limit information to the UF/Prop uC. The limits are based on the concentrate type (acetate or bicarb), the proportioning ratio, and the desired sodium concentration.

  - The UF/Prop uC monitors C1 for an acetate (or "A" part with bicarb treatment) conductivity, alarming if the conductivity is outside of the "A" part limits.

  - The UF/Prop uC monitors the difference between the C2 and C1 conductivity measurements for a "B" part (with bicarb) conductivity, alarming if the conductivity is outside of the "B" part limits.

  - The UF/Prop uC directly deactivates the bypass valve (removing flow through the dialyzer) during a backup conductivity alarm.

  - The UF/Prop uC indirectly (via the 80XX uP) triggers an audible and visual alarm.

- Bypass Valve Fail Detection

  (see same section under Temperature System Components)

Saf ty Discussion

Since the UF/Prop uC is responsible for controlling the concentration, the Misc I/O uC provides an independent safety system. The safety system contains four major components who's functions must be verified at the beginning of each treatment. These are:

1. The Misc I/O uC's ability to measure the dialysate conductivity using the primary ("dialysate") conductivity probe (C3)

2. The Misc I/O uC's ability to calculate conductivity alarm limits that are ±5% of the measured conductivity

3. The Misc I/O uC's ability to recognize a conductivity outside the desired alarm limits

4. The Misc I/O uC's ability to deactivate the bypass valve

The following tests are therefore performed during the pretreatment testing.

1. **C3 measurement accuracy test** - The 80XX uP compares the Misc I/O uC's C3 measurement with the UF/Prop uC's measurement of the C2 conductivity probe and verifies that they are within 0.3 mS/cm of each other. The C3 conductivity measurement is continuously displayed on the front panel and must be verified in the Self Test Mode, allowing user verification of its accuracy.

2. **Alarm limit calculation test** - The user is requested to verify that the displayed conductivity is acceptable. After this verification is received, the 80XX uP commands the Misc I/O uC to calculate alarm limits at ±5% around the current conductivity. The 80XX uP then reads these limits and verifies that they are correct.

3. **Misc I/O alarm test** - The 80XX uP consecutively generates both primary conductivity alarms by first setting the upper alarm limit to a value below the current conductivity, and then by setting the lower alarm limit to a value above the current conductivity. An upper alarm is also generated through hardware by forcing the conductivity amplifier output to a high value. In each case, a reported alarm condition from the Misc I/O uC is verified by the 80XX uP.

4. **Bypass verification** - During the alarm conditions described in item 3 above, the 80XX uP verifies bypass by testing for a no flow condition through the dialyzer.

The following additional tests are also performed during the pretreatment testing to guarantee a fully functional system.

5. **UF/Prop alarm test** - Similar to the Misc I/O alarm test described in item #3 above, the "A" and "B" probe redundant alarms in the UF/Prop uC are tested by moving their alarm limits so that they force high and low redundant alarm conditions. The alarm r sponses for each case are verified.

6. **80XX uP alarm t st** - The 80XX uP tests the backup alarm limits by moving them so that they force high and low backup alarm conditions. An alarm response is verified for each.

Venous Pr ssure

Function

Monitors the pressure in the venous drip chamber, and latches an alarm condition when the pressure is outside of set limits. An alarm condition stops the blood pump and clamps the line clamp.

Safety Requirements

A protective system to protect the patient from extracorporeal blood loss to the environment which: stops the blood pump, clamps the line clamp, activates audible and visual alarms, sets the ultrafiltration rate to zero. This system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient. The minimum low pressure limit must not be less than +10 mmHg.

System Components

- Venous and arterial pressure transducers
- The Blood Pump uC measures the venous and arterial pressure transducer outputs and provides these measurements to the 80XX uP.
- The 80XX uP calibrates the venous pressure reading and compares it with alarm limits that form a ±50 mmHg window. On detection of a venous alarm condition, the 80XX uP creates an audio and visual alarm, commands the Blood Pump uC to stop the blood pump, and commands the Misc I/O uC to clamp the line clamp (which in turn redundantly stops the blood pump). An alarm condition is maintained until a reset is commanded by the user (via the 80XX uP).

Safety Discussion

The venous alarm window is increased to ±200 mmHg when the blood pump is off to prevent the occurance of an alarm as a result of the blood pump being turned off. The alarm window closes again to ±50 mmHg around the current venous pressure ten seconds after the blood pump starts, which allows the venous pressure time to stabilize.

In addition, during a Prime Disarm mode of operation, the venous window is always ±200 mmHg to allow convenience in setting up and priming the blood lines. This mode automatically times out after five minutes.

The safety system contains three major components who's functions must be verified at the beginning of each treatment. These are:

1. The 80XX uP's ability to obtain the venous pressure
2. The 80XX uP's ability to recognize a pressure outside of the alarm limits
3. The 80XX uP's ability to stop the blood pump

The following tests are theref re performed during Self Test.

1. The 80XX uP vents th venous and arterial pressure transducers together (via the Blood Pump controller) and

pumps them to a positive pressure between 100 mmHg and 500 mmHg. The accuracy of the two monitors is compared. If the pressures are not within 50 mmHg of each other the test fails.

2. The 80XX uP creates both high and low venous pressure alarms by pumping the venous pressure above and below the limit window using the level adjust pump. An alarm response is verified for each. For the first alarm response, the user is asked to verify the existence of audible and visual alarms.

3. For each alarm occurrence, the 80XX uP receives verification from the Blood Pump uC that the blood pump is stopped. This verification is based on the absence of the blood pump motor tachometer signal (which is independent of the pump's commanded state).

The following additional tests are also performed during the pretreatment testing to guarantee a fully functional system.

4. The 80XX uP creates both high and low arterial pressure alarms using the level adjust pump, with the alarm responses verified.

5. The 80XX uP verifies the performance of the level adjust pump by ensuring that when it pumps up both the arterial and venous pressure transducers for two seconds that the resulting pressure increase is between 100 and 500 mmHg.

Air Detector

Function

Monitors for the presence of air in the venous blood line upstream of the line clamp, and latches an alarm condition when an air bubble is detected. An alarm condition stops the blood pump and clamps the line clamp.

Safety Requirements

A protective system to protect the patient from air infusion which:

- Stops the blood pump
- Clamps the line clamp
- Activates audible and visual alarms
- Sets the ultrafiltration rate to zero during an alarm condition
- Does not have a single fault mode that disables the alarm that is not immediately detectible
- Does not have a double fault mode that disables the alarm, where either of the two faults cannot be detected prior to each treatment.
- This system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient.

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System Compon nts

- An ultrasonic transducer transmitter, which the 80XX uP can disable for testing.

- Ultrasonic air detection sensor, consisting of one ultrasonic transducer receiver, which drives the input of two independent and parallel amplifiers. The output of the two amplifiers are referred to as output #1 and output #2.

- Air alarm output #1 is monitored by the Misc I/O uC for air and bubble detection.

- The Misc I/O uC directly clamps the line clamp.

- The Misc I/O uC directly stops the blood pump.

- Air alarm output #2 latches a hardware latch, which directly clamps the line clamp.

- When the line clamp clamps, an optical sensor disables the blood pump.

- Both the Misc I/O uC and the 80XX uP must independently act to reset or disable the hardware latch.

- An air disarm mode (in Prime Mode only), initiated by the user, disables all air alarms for 5 minutes, as timed by the 80XX uP. Neither the 80XX uP nor the Misc I/O uC will enter the disarm mode from a non-Prime Mode.

Safety Discussion

A single ultrasonic transmitter transducer and a single ultrasonic receiver transducer are used because these devices do not have conceivable nondetectable failure modes.

The air alarm can be disabled for a limited time period in the Prime Mode for the purposes of setting up the blood lines and dialyzer. During this disarm period, the audio alarm beeps every thirty seconds. The operator is discouraged from dialyzing in the Prime Mode because of the following machine conditions:

- UF rate is limited to 0.5 liter per hour (L/h), with a default rate of 0. The calculated UF rate based on treatment time and desired UF volume is not activated until the Dialyze Mode begins.

- The UF rate will not automatically drop to zero when the desired UF volume is achieved.

- The accumulated treatment time, UF, blood, and heparin parameters are forced to zero until the Dialyze Mode begins.

The safety system contains a major component who's functions must be verified at the beginning of each treatment. This is:

- The ability of the hardware air detector (from the #2 output) to detect air and in response to clamp the line clamp and stop the blood pump.

The following test is therefore performed during the Self Test.

- With the ultrasonic transmitter disabled (with or without fluid filled tubing in the detector housing) and the software air detector (from output #1) disabled, the 80XX uP verifies that when the

hardware air detector (from output #2) is enabled (not reset), that the line clamp is clamped and the blood pump is stopped. This is done twice, once with just the 80XX uP enabling it, and once with just the Misc I/O uC enabling it.

- This system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient.

Blood Leak Detector

Function

Monitors for the presence of blood in the dialysate down stream of the dialyzer. When blood is detected, an alarm condition is latched, which stops the blood pump.

Safety Requirements

A protective system to protect the patient from extracorporeal blood loss through the dialyzer which: can detect a leak rate of 0.5 mL/min when in alarm stops the blood pump, activates audible and visual alarms, sets the ultrafiltration rate to zero during an alarm condition. This system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient.

System Components

- Optical blood leak detector, utilizing a green LED light source and a cadmium sulfide light detector.
- The Misc I/O uC monitors an analog level representing the amount of light on the light detector, and creates an alarm condition when the light level drops below a calibrated threshold.
- The Misc I/O uC can adjust the intensity of the LED light source for purposes of testing and varying the blood leak threshold.
- The Misc I/O uC directly stops the blood pump and indirectly (via the 80XX uP) clamps the line clamp.

Safety Discussion

The safety system contains two major components who's functions must be verified at the beginning of each treatment. These are:

1. The Misc I/O uC's ability to detect a drop in light level at the light detector
2. The Misc I/O uC's ability to stop the blood pump

The following tests are therefore performed during the pretreatment testing.

1. The 80XX uP reduces the light intensity of the LED light source (via the Misc I/O uC) to 80% of its normal operating level.
2. The 80XX uP verifies that the Misc I/O uC reports a blood leak alarm condition in response to item #1, and that the blood pump stops (via the Blood Pump uC).

Main Controllers (80XX uP, 8040 uCs)

Function

The 80XX supervises the operation of the machine, including maintaining the machine state (i.e.; Rinse, Disinfect, Dialyze, etc), performing self testing, handling calibrations, and providing the user interface.

The 8040 microcontrollers handle specific machine related functions for the Blood Pump, UF/ Proportioning, and Misc I/O Systems. In addition, each controller functions as a watchdog for the 80XX, forcing the system into a nonfunctional safe state if the 80XX discontinues its interprocessor communication.

Safety Requirements

As related to functions that are elements of safety systems, single failures should not result in an immediate hazard, and single failures that are hazardous when combined with a second failure should be detectible at the beginning of every treatment.

System Components

- 80XX microprocessor
- Program memory (ROM)
- Temporary memory (RAM)
- Interprocessor communication system
- Blood Pump Controller 8040 and program ROM
- UF/Prop Controller 8040 and program ROM
- Misc I/O Controller 8040 and program ROM
- Microcontroller A/D converters
- Hardware watchdog

Safety Discussion

The 80XX performs the following safety related functions:

- Saves and retrieves calibration constants in the nonvolatile memory (NVRAM), and uses these constants during machine operation. Monitors the arterial and venous pressures, and generates alarms when they violate their alarm limits. The alarm response includes clamping of the line clamp (via the Misc I/O uC) and stopping the blood pump (via the Blood Pump uC).

- Calculates the TMP (transmembrane pressure) by subtracting the dialysate pressure from the venous pressure. Compares the results with the TMP alarm limits, generating an alarm if a violation is detected.

- Maintains communication with the three microcontrollers, providing them calibration, machine state, and operational parameters. In addition, the communication system serves as a watchdog, ensuring that the 80XX and the 8040 controllers are functioning.

- Performs the pretreatment selftest.

- Controls the active machine state, which can be Calibrate, Rinse, Self Test, Prime, Prime Disarm, or Dialyze.

- Accepts operating information and parameters from the user via the CRT (video display) touch screen (e.g. blood flow rate, dialysate temperature, UF rate).

- Displays operating conditions and status on the video display.

Of these listed functions, the following are verified during selftests for other safety systems.

- The use of the nonvolatile memory for calibrations. The "Nonvolatile Memory" section discusses the nonvolatile memory integrity, and calibrations that have safety significance (e.g.; conductivity) are verified as part of the associated safety function's self test (conductivity calibration failure would cause the conductivity self test to fail due to insufficient accuracy).

- The arterial and venous pressure alarms.

- The TMP alarm.

Except for the watchdog functions, the 8040 microcontrollers handle safety related functions that are included in the other sections of this report.

To ensure general integrity of the control system, the following tests are performed during the pretreatment testing.

1. The watchdog function handled by each 8040 microcontroller is tested by individually halting communication to each 8040 and verifying a resulting system shutdown condition.

2. The system's A/D (analog to digital) converters are compared with each other to verify accuracy. Each of the three controller systems (BP, UF, and I/O) utilize D/A converters in a successive approximation algorithm to provide A/D functions. For Self Test purposes, the D/A output from the Misc I/O controller can be connected to the A/D inputs of the BP and UF controllers simultaneously. Self testing involves outputting a range of levels through the Misc I/O D/A converter and verifying that similar levels are read by the BP and UF A/D converters.

3. A self test verification test consists of verifying that each self test has successfully executed prior to exiting the Self Test state.

In addition to these pretreatment self tests, the following safety testing is also performed.

4. An inadvertent transition from the Dialyze state to Rinse is potentially safety critical, since the air detector would be disabled and the bypass valve would cycle independent of temperature or conductivity. However, dialysis during Rinse is prevented by disabling the blood pump when the dialysate lines are not both on their rinse fittings. In addition to this safeguard, before the air detector can be disarmed or the bypass valve can cycle, both the 80XX and the Misc I/O 8040 must be in the Rinse state. Before either enters the Rinse

state from Dialyze, the operator must press the RINSE and RINSE VERIFY buttons and both dialyzer lines must be verified on their rinse fittings (using the optical interlock switches). The 80XX filters out the Rinse request from the Misc I/O C ntroller when the dialyzer line interlocks are not in the proper state. The only way the Misc I/O Controller can receive a Rinse request without the proper interlock condition being met is if a failure exists in the system logic. If this situation does occur, then the Misc I/O Controller activates the system shutdown line.

Power Supply

Function

Provide low voltage power to the entire machine.

Safety Requirements

The raising or lowering of any supply voltage shall not place the machine in an unsafe state.

System Components

- +5V regulated supply
- +12V regulated supply
- −12V regulated supply
- +24V unregulated supply

Safety Discussion

The +5V supply is used to power the digital logic, including the 80XX microprocessor and the 8040 microcontrollers. The ±12 V supplies power analog circuitry, and the +24 V provides power to power loads, such as valve solenoids and motors.

All three of the microcontrollers measure the +5 V supply level. They also measure a voltage that is derived from the combination of the +12 V and −12 V supplies, which provides indication if either one changes. The +24 V supply is measured by the Blood Pump Controller.

If the +5 V supply suddenly changes to a level that incapacitates the +5 V control logic, then the hardware watchdog (which the Misc I/O Controller services) times out and forces a system shutdown.

Touch Screen

Function

Provide for user control of the machine through sensing of touch contact on the CRT surface (video display).

Safety Requirements

Critical control and alarm parameters entered via the touch screen should be ensured to be without error.

System Components

- Touch screen pad mounted to CRT face 8039 touch screen controller (or vendor supplied controller)

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- Serial keyboard interface to 80XX uP (or bus interface with vendor controller)

Saf ty Discussi n

- Concentrate level
- Heparin pump rate
- UF rate
- Dialysate temperature

When these parameters are entered by the operator, through software checking it is redundantly verified that the parameter that is displayed on the screen is identical to the value that is ultimately stored and used by the machine. When the data is being input by the operator, it is placed into two redundant memory locations. One of these locations is used to derive the value being displayed on the screen. The other location is copied to the final destination of the parameter when the entry is complete. The value is then read back from its final destination, and verified to be equal to the value that was used for the display.

The control system is designed to protect against random touches, which may result from someone bumping up against the screen, or from a failing touch screen. No therapy changes can result from single touches, by requiring that all such changes be verified with an addition touch. An example is the blood pump rate selection. Through a single touch to a rate select area on the screen, a new blood pump rate can be selected. However, the new rate is not implemented until a Verify button is pressed. If the Verify button is not pressed, then after a timeout period the new rate selection is request is not acted upon. All changes in therapy are displayed on the CRT and are available to the operator for verification after they are entered.

Nonvolatile Memory

Function

Provides a modifiable yet nonvolatile memory for calibration and machine state information.

Safety Requirements

Critical data stored in the nonvolatile memory should be ensured to be without error.

System Components

- 80XX uP writes to and reads from memory
- 8K of static CMOS RAM
- Battery energy storage

Safety Discussion

All data stored in the nonvolatile memory will be stored twice, with one version complimented. Every time data in the memory is used, the two versions will be compared.

RS-232 Interface

Functi n

Provides a communication port through which data can be transferred to an external computer.

Safety Requirements

Because an external device of unknown characteristics can be attached to this interface, the interface must meet the 4 KV isolation requirement that is imposed on the primary line voltage components.

In addition, if the machine operation can be controlled through this interface, then the safety of the source of the control data and the data path must be ensured.

System Components

- Isolated RS-232 interface
- Isolated low voltage for powering the interface

Safety Discussion

Currently the RS-232 interface is configured for transmitting data from the machine for care provider reference purposes. Therefore there is no safety criticallity associated with this interface.

UF Protective System

Function

Ensures that the UF system is functioning properly.

Safety Requirements

A protective system independent of any control system which prevents the output of the equipment from varying from the desired value of the controlling parameter and causing a hazard to the patient. An acceptable method for complying is to measure and alarm off of the transmembrane pressure (TMP).

The TMP alarm system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient.

System Components

- Dialysate pressure transducer (pre dialyzer).
- Venous pressure transducer.
- The Blood Pump uC monitors the venous pressure.
- The Misc I/O uC monitors the dialysate pressure.
- The 80XX uP compares the dialysate pressure minus the venous pressure (TMP) with ±35mmHg alarm limits.
- The 80XX uP generates an audible and visual alarm during a TMP alarm condition.

Safety Discussion

The UF Control system is responsible for controlling the UF rate, as well as the dialysate flow control components which are responsible for guaranteeing a balanced volumetric system. The TMP alarm system is independent, consisting of the dialysate pressure measured by the Misc I/O Controller, and the venous pressure measured by the Blood Pump Controller.

The following pretreatment tests are performed, which not only verify the function of the TMP alarm, but also verify the function of the volumetric control system. During these tests, there is no dialyzer connected to the machine.

1. The 80XX calculation of TMP is redundantly calculated, and verified to be accurate.

2. The function of the UF metering device is tested by removing two metered strokes and verifying that the dialysate pressure is reduced by an expected amount.

3. The accuracy of the volumetric control system is verified by measuring the dialysate pressure drift rate over a period of time with a zero UF rate.

4. The high TMP alarm is tested by setting the high limit below the current TMP, and the low TMP alarm is tested by setting the low limit above the current TMP. The high limit is also tested by increasing the TMP through the removal of UF until the upper TMP limit is violated.

Programmable Sodium

Function

Allow the sodium level to change throughout the treatment based on information entered by the user at the beginning of the treatment. As the sodium level is changed, the conductivity alarm limits are also changed accordingly.

Safety Requirements

Single failures should not result in an immediate hazard, and single failures that are hazardous when combined with a second failure should be detectible at the beginning of every treatment.

System Components

* 80XX uP

* Nonvolatile memory

Safety Discussion

This system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient. The following safety critical tasks are involved with this function:

1. Accepting program data from the operator

2. M difying the proporti ning rate at times and by am unts dictated by the entered data.

3. Modifying the conductivity alarms to prevent alarm occurrences during the proportioning rate transitions.

Programmable UF

Function

Allow the UF rate to change throughout the treatment based on information entered by the user at the beginning of the treatment.

Safety Requirements

Single failures should not result in an immediate hazard, and single failures that are hazardous when combined with a second failure should be detectible at the beginning of every treatment.

System Components

- 80XX uP
- Nonvolatile memory

Safety Discussion

This system is tested prior to each treatment during Self Test and if found to be non-functional, the machine will not allow the opertor to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient. The following safety critical tasks are involved with this function:

1. Accepting program data from the operator
2. Modifying the UF rate at times and by amounts dictated by the entered data.

External Memory Card

Function

Provides an external memory device which can be written to or read from by the machine. Treatment data can be written which can later be analyzed using a computer. Calibration data can be saved for later recall after hardware maintenance. A specially coded card can serve as a tool for technician access to special calibration and troubleshooting operating modes.

Safety Requirements

Since this device has no control function, it is not considered a safety critical device.

Self Test Summary

During Self Test, the machine automatically performs the machine related pre-dialysis "operator tests." The essential alarms, monitors and functions are checked. If any test fails, the machine will not allow the operator to initiate the Prime or Dialyze Modes there by preventing the operator from dialyzing a patient.

Below are the tests with their relevant parameters that are included in the Self Test routine.

Venous/Arterial Pressure Test

Background

This t st is primarily intended to verify the functionality of the high and low venous and arterial pressure alarms. The testing results in verification of the following additional functions:

- User verification of the functionality of the main alarm lamp and audio alarm (during high venous alarm only). Functionality of the line clamp (tested during high venous alarm). Verification of the relative accuracy of the arterial and venous pressure measurement systems. Functionality of the level adjust system. Verification that the state machine is alerted of all pressure alarms. Verification that the blood pump stops during during all pressure alarms.

- The line clamp is disabled after the first high venous alarm condition to reduce the noise level during Self Test.

Test Sequence

Test Setup

The operator is asked to verify that the pressure luers are plugged. It is verified that no preexisting alarms exist, and the blood pump is turned on. The arterial and venous pressure alarm limits are closed to ±50 mmHg around the current pressures.

High Venous Test and Audio and Main Alarm Lamp Function

The level adjust pump is run for two seconds to increase the venous pressure and cause an alarm. After the alarm occurs, the operator is asked to verify the audio alarm and main alarm lamp response. The venous alarm window is then set to ±200 mmHg around the current pressure, and the alarm is reset.

High Arterial Test

The arterial and venous pressure transducers are vented together, increasing the arterial pressure and decreasing the venous pressure. After the arterial alarm occurs, both the venous and arterial pressure limits are set to ±50 mmHg around the current pressures. The alarm is then reset.

Level Adjust/Pressure Accuracy Test

It is then verified that the venous and arterial pressures are within 50 mmHg of each other, to verify their relative accuracies. To verify the level adjust system, it is also confirmed that the venous pressure is greater than 100 mmHg and less than 500 mmHg.

Low Venous Test

The pressure transducers are then isolated from each other, and the venous pressure is decreased by running the level adjust pump for two seconds. After the alarm, the venous pressure limits are set to ±200 mmHg around the current pressure, and the alarm is reset.

Low Arterial Test

The arterial and venous pressure transducers are vented together, decreasing the arterial pressure and increasing the venous pressure.

After the arterial alarm occurs, the arterial pressure limit is set to ±200 mmHg around the current pressure. The alarm is then reset.

Blood Leak Detector Test

Background

This test verifies that the blood leak detector alarm is functional by simulating a blood leak. The blood leak detector consists of an LED (light source) and a photocell (light detector). During a blood leak, the light level at the photocell is dimmed, resulting in the detection of a blood leak. During this test, the LED light level is dimmed, and a blood leak response is verified.

The following blood leak alarm responses are verified by the blood leak self test:

- The acknowledgement of the blood leak alarm by the state machine.

- The commanding of the alarm lamp to flash.

- The stopping of the blood pump.

Test Sequence

Test Setup

It is verified that no preexisting blood leak alarms exist and that the blood pump is turned on.

Generation of Blood Leak Alarm

The LED light level is decreased to 80% of the non-blood alarm threshold level. The alarm responses should result within nine seconds.

Resetting of Alarm

The LED light level is restored to its original value, and after a two second delay, the alarm is reset. The alarm is required to reset within nine seconds.

UF Test

Background

The UF Self Test checks for leaks in the UF system and for functionality of the UF removal metering device. To accomplish this, the system is closed by isolated the dialysate pressure relief valve, and approximately 3 mL of fluid is removed via two strokes of the UF removal metering device. The dialysate pressure must decrease from its vented pressure by 95 to 330 mmHg. Stability is then tested by averaging the pressure over 20 seconds, waiting 20 seconds, and then taking a second average over 20 seconds. The two averaged pressure readings must be within 50 mmHg of each other. To begin this self test, the vented dialysate pressure must be between −100 and +100 mmHg and the dialysate lines must be on the rinse block.

This test also checks the TMP calculation by subtracting the dialysate pressure from the venous pressure and comparing this result to the TMP value the host calculates and displays. These two values must be within 10 mmHg.

Test Sequence

Test Vented Dialysate Pressure

The dialysate pressure relief valve is opened and the dialysate pressure must measure between –100 and +100 mmHg.

TMP Calculation Test

TMP is calculated from the dialysate and venous pressures. This value must be within 10 mmHg of the host calculated and displayed TMP. The high TMP alarm limit is set to +700 mmHg and the low limit to –700 mmHg.

UF Integrity Test

The dialysate pressure relief valve is closed and the approximately 3 mL of fluid is removed via the UF removal metering device. The average dialysate pressure is measured over 20 seconds. This average pressure must be 95 mmHg to 330 mmHg lower than the vented pressure. After 20 seconds the average pressure is measured again over a 20 second period. The two average pressure readings must be within 50 mmHg of each other to pass the stability test. The dialysate pressure relief valve is then opened.

TMP Limit Test

Background

This test checks the TMP alarm limits.

Test Sequence

Delay to Vent Dialysate Pressure

The dialysate pressure relief valve was opened at the end of the UF Test. There is a 20 second delay before this test begins to allow the pressure time to vent.

Test Vented Dialysate Pressure

The dialysate pressure relief valve is opened and the dialysate pressure must measure between ±100 mmHg. The high TMP limit is set to +700 mmHg and the low limit to –700 mmHg.

Measure Average TMP

The average TMP is measured over a 20 second period.

High TMP Alarm Test

The high alarm is verified by decreasing the high alarm limit 100 mmHg below the average TMP. The alarm is verified and the limit is reset. It is verified the alarm clears.

Low TMP Alarm Test

The low alarm is verified by increasing the low alarm limit 100 mmHg above the average TMP. The alarm is verified and the limit is reset. It is verified the alarm clears.

Second High TMP Alarm T st

The high alarm limit is set to 200 mmHg above the average TMP. The dialysate pressure relief valve is closed and fluid is removed via the UF removal metering device until the high TMP alarm limit is

violated creating an alarm. The dialysate pressure relief valve is then opened. It is verified the alarm clears.

Res t Limits

The high limit is set to +500 mmHg and the low limit is set to –80 mmHg.

Temperature Test

Background

There are two separate temperataure alarms that are verified. These are:

- The Primary alarm is set by the Miscellaneous IO controller board which monitors the primary temperature probe. When this limit is violated the temperature window blinks and the word ALARM is displayed above the window.

- The Redundant high alarm is set by UF controller board which monitors the "A" and "B" temperature probes. If either of these probes is in alarm, the temperature window blinks and the word BACKUP is displayed above the window. There is no redundant low alarm.

Test Sequence

Note: All alarm verifications include checking the controller and host alarm, the main alarm lamp and bypass response.

Primary High Alarm

The primary high alarm is verified by decreasing the high alarm limit 0.5°C below the current temperature.

Primary Low Alarm

The primary low alarm is verified by increasing the low alarm limit 0.5°C above the current temperature.

Redundant High Alarm

The redundant high alarm is verified by decreasing the reduntant high alarm limit 1°C below the current temperature.

Temperature Stability

To insure that the temperature is stable, it is verified that the temperature at the primary probe and at the "B" probe are within 1°C of each other.

Conductivity Test

Background

There are three separate conductivity alarms that are verified. These are:

- The Primary alarm is set by the Miscellaneous IO controller board which monitors the primary conductivity probe. These are the tightest limits, set to ±5% during the last Self Test, Conductivity Verification. However, at the time conductivity selftest is performed, these limits are still at their wide default setting. When this limit is violated the conductivity window blinks and the w rd ALARM is displayed above the window.

- The Redundant alarm is set by UF controller board which monitors the "A" and "B" conductivity probes. If either of these probes are in alarm, the conductivity window blinks and the word BACKUP is displayed above the window.

- The host (80XX microprocessor) has technician settable alarm limits, with default values of 12 mS/cm and 16 mS/cm. If the conductivity reading from the primary conductivity probe exceeds these limits, the conductivity window blinks (no message is written above the window).

Note: The dialysate pressure relief valve is closed during this Self Test.

Test Sequence

Note: All alarm verifications include checking the controller and host alarm, the main alarm lamp and bypass response.

Simulated High Conductivity /High Temperature

A high conductivity and temperature is simulated with hardware forcing the conductivity up to ~20 mS/cm and the temperature to ~50°C. The primary and host conductivity alarms, and the primary temperature alarm are verified.

Primary High Alarm

The primary high alarm is verified by decreasing the high alarm limit 0.5 mS/cm below the current conductivity.

Primary Low Alarm

The primary low alarm is verified by increasing the low alarm limit 0.5 mS/cm above the current conductivity.

Redundant High Alarm

The redundant high alarms ("A" and "B") are verified by decreasing their high alarm limits 0.5 mS/cm below their respective current conductivity values.

Redundant Low Alarm

The redundant low alarms ("A" and "B") are verified by increasing their low alarm limits 0.5 mS/cm above their respective current conductivity values. Also at this time, the redundant bypass function is verified by checking that the flow sensor indicates no flow.

Host High Alarm

The host high alarm is verified by decreasing the high alarm limit 0.5 mS/cm below the current conductivity.

Host Low Alarm

The host low alarm is verified by increasing the low alarm limit 0.5 mS/cm above the current conductivity.

Conductivity Stability

To insure that the conductivity is stable, it is verified that the conductivity at the primary probe and at the "B" probe are within 3 mS/cm of each other.

Air Detector Test

Background

The air detector test verifies the functionality of the backup air detector, and also the primary air detector if fluid filled tubing is installed in the air detector.

The primary air detector is implemented in software, and as a result has a programmable sensitivity. Its nominal sensitivity is such that it would detect a 10 mL bubble. The primary air alarm cannot be disabled, however its alarm response (i.e.; line clamp clamped, stopped blood pump, audio alarm, etc.) can be disabled.

The backup air detector is completely implemented in hardware, with a nonadjustable sensitivity. Its nominal sensitivity allows it to detect a 300 mL bubble, which is adequate to prevent a major injury to the patient. The backup air detector's alarm response of clamping the line clamp and stopping the blood pump is completely implemented in hardware. The backup air detector can be disabled only when two microprocessors (the 80XX host and the 8040 Misc I/O Controller) both activate their respective disable lines simultaneously. The self test verifies individually that each microprocessor can enable the backup alarm. When the Misc I/O Controller is enabling the alarm, it is referred to as "alarm #1", and when the 80XX is enabling it, it is referred to as "alarm #2".

Both air detectors are based on passing an ultrasonic signal through the blood line and detecting a sudden drop in the resulting signal level. The backup air detector is tested by disabling the generation of the ultrasonic signal, enabling the backup alarm, and verifying that the line clamp clamps. The primary alarm is tested by disabling the ultrasonic signal for 20 msec verifying a primary air alarm is reported to the state machine.

Test Sequence

Test Setup

The backup air alarm is disabled, and the alarm responses to the primary alarm are disabled. It is verified that the line clamp is open.

Backup Alarm Test (#1)

The backup alarm is enabled via the Misc I/O microprocessor only, the air detector ultrasonic signal generator is disabled, and an alarm response is verified to occur. The verified alarm response consists of a clamped line clamp, and a reported primary and backup alarm to the state machine. The ultrasonic signal is then enabled, the backup alarm is disabled, and the alarm is reset.

Backup Alarm Test (#2)

The backup alarm is enabled via the host 80XX microprocessor only, the air detector ultrasonic signal generator is disabled, and an alarm response is again verified to occur within nine seconds. The ultrasonic signal is then enabled, the backup alarm is disabled, and the alarm is reset.

Bubbl Test

After the previous air alarm was reset, the existance of a primary alarm is then tested. If a primary alarm exists, then it is assumed that the air detector is not loaded with fluid filled tubing, and therefore the bubble test is skipped. If a primary alarm does not exist, then the bubble test is initiated by disabling the ultrasonic signal for 20 msec. It is then verified that a primary air alarm is reported to the state machine. The alarm is then reset.

Conductivity Verify Test

Background

The conductivity verify test is executed only if all other Self Test routines have passed.

At this time the operator is asked to verify that the displayed conductivity is correct. Prior to this, the primary conductivity limits are at their default values of 12 mS/cm and 16 mS/cm. After the conductivity is verified, the primary conductivity alarm limits are set to ±5% around the current conductivity.

The "A" probe conductivity is verified by the UF Controller to be within 10% of a calculated nominal value based on concentrate type and proportioning ratio. Prior to this, the "A" probe conductivity limits are at their default values of ±14.3% around this calculated nominal conductivity. After this verification, the "A" probe limits are set to ±14.3% around the current conductivity.

The "B" probe conductivity is also verified by the UF Controller to be within 10% of a calculated nominal value. The conductivity limits of the "B" probe are handled differently depending on whether the proportioning mode is acetate or bicarb. In the acetate mode, the default "B" probe limits are ±14.3% around the calculated nominal value. After verification, the "B" probe conductivity limits are set to 14.3% around the current conductivity. In the bicarb mode, the alarm limits are set around the "B" part conductivity, which is the difference between the "B" and "A" probe conductivies. The default "B" part limits are set to ±2 mS/cm around the calculated nominal "B" part conductivity. After verification, the "B" part conductivity limits are set to ±2 mS/cm around the current "B" part conductivity.

Test Sequence

Verify Conductivity

Operator presses yes or no button to verify that the displayed conductivity is correct.

"A" and "B" Probe Conductivity Range

Verifies "A" and "B" probe conductivities to be within expected ranges.

Verify 5% Limits

The 5% limits are calculated and compared to the 5% limits calculated by the Miscellaneous IO controller. The two calculations must yield limits within 0.1 mS/cm of each other.

Lu r Test

Background

Since the blood pressure test requires that the blood pressure luers be plugged, this test verifies that the luers are unplugged before Prime Mode is entered.

This test is not executed if blood pressure test fails.

Test Sequence

Display a message asking the operator if the luers are vented.

If the operator presses "YES", then the test passes.

If "NO" is pressed, then the test fails.

Test Results

Blood Pump

Power Supply Measurement

Introduction

To allow for checking of the power supply values on the Blood Pump Controller board by the host, they are read via the analog to digital converter and their values are stored in memory. The +5 and +24 volt power supply analog inputs are attenuated by resistor dividers to provide nominal values at 3.00 V and 3.42 V, respectively. The +12 volt supply and –12 volt supply are measured on one analog input by having the supplys at either end of a resistor divider with a nominal input voltage of 2.84 volts.

The accuracy of the measurement is dependent on the the resistor divider tolerance (using 1% resistors), the resolution and offset errors of the 8 bit analog to digital conversion. The resolution of the 8 bit A/D measurement is: $(1/255) * 5 V = 19.6$ mV/bit. As a 10 bit monotonic D/A is used, this contributes to a negative error only. The maximum offset error is ±31.5 mV.

The tolerances for the 5 V, 24 V and ±12 V resistor dividers are ±24 mV, ±59 mV, and ±113 mV respectively excluding supply voltage variations. Therefore, the total tolerances are:

5 V supply: –75.1 to 55.5 mV

24 V supply: –110.1 to 90.5 mV

±12 V supply: –164.1 to 144.5 mV

Data

To determine the accuracy of the power supply readings the actual power supply and analog input voltages were measured and the readings stored in memory were recorded.

+5 V ANALOG INPUT Expected (±.01V)	+5 V ANALOG INPUT	CALC VOLT **VALUE	% DIFF VOLT	ADC VAR EXP. MEAS	CALC SUPPLY ***	% DIFF
2.856	*2.87	2.87	0.0	147	4.79	3.9

* The supply voltage was 4.76 volts ±.02 V (measured on high side of R13 n the Blood Pump Controller board). The low analog input voltage is a result of the low power supply voltage. The expected analog voltage is calculat d from the measured supply voltage.

** CALC VOLTAGE = (ADC value)/(ADC range) * (Full scale voltage) = (147/255) * 5 V(1020/1023) = 2.87 V

*** CALC SUPPLY VOLTAGE = CALC VOLTAGE * 5 V/3 V = 4.79 V

+12/-12V ANALOG INPUT EXP (±.01 V)	+12/-12V ANALOG INPUT MEAS	ADC VARIABLE VALUE	CALC *VOLTAGE	% DIFF
2.744	*2.74	141	2.76	0.7

* The supply voltages were 12.00 volts (measured on high side of R15 on th Blood Pump Controller board) and 12.25 volts (measured on low side of R16 on BP Controller board). The difference between the nominal input voltage and the measured input voltage (2.84 V – 2.74 V = 0.10 V) can be attributed to the –12 V supply being at –12.25 V.

+24 V ANALOG INPUT EXP. (±.01 V)	+24 V ANALOG INPUT MEAS	CALC VOLT **VALUE	% DIFF VOLT •••	ADC VAR	CALC SUPPLY	% DIFF
3.249	*3.26	3.25 - 0.0	166 - 22.8 - 0.0		3.27	167 22.9

* This voltage was measured on RZ3 pin 10 on the Blood Pump Controller board. The +24 volt supply was measured at 22.82 ±0.01 volts at the high side of R26 on the Blood Pump Power board. The measured voltage at the analog input is 0.16 V below the nominal input voltage of 3.42 V. This can be attributed to the low supply voltage and resistor tolerance.

Summary

The calculated voltages for the + 5, 12 and –12 volt supplies were within 10 mV and 20 mV of the measured input voltages to the A/D converter, respectively.

This difference may be attributed to the tolerance of the measurement (±10 mV) and/or the tolerance of the AD conversion (19.6 mV). The calculated voltage for the +24 V supply was the same as the measured input voltage.

This data shows that the accuracy of the power supply measurements are within the expected tolerance range.

Heparin Pump Controller Performance

Description

The purpose of the heparin pump system is to deliver an operator specified amount of heparin to the patient. The operator may select the heparin pump to operate in a normal mode and deliver 0.5 to 5.5 mL/h or a high speed mode to deliver a bolus amount of heparin quickly. (The size of the bolus is a software setting available to technicians.)

The heparin pump controller system is comprised of the following major components:

Description	Location
User parameter entry	Host controller
Motor power driver circuitry	Bld Pmp Power board
Optical end of stroke sensor	On rack/pinion fixture
Optical rack engage sensor	On engage arm fixture
Software speed control	Bld Pmp Controller bd
Software overspeed check	IO Controller board

Heparin delivery is accomplished by stepping a stepper motor which rotates the pinion of a rack and pinion mechanism. The pinion moves the rack, and the mechanical fixture is such that the plunger of the

heparin syringe moves the same distance. Therefore, the amount of heparin delivered is a function of the diameter of the syringe and the distance traveled by the rack.

There are two optical sensor to provide information about the state of the heparin pump. The engage sensor detects when the front panel syringe holder arm is in the disengage position. If it is in the disengage position a DISENGAGE message is displayed on the front panel (CRT). The end-of-stroke sensor detects when the pinion is raised up on the rack, which results when the gear teeth are no longer meshed. This condition occurs if the syringe plunger is at the bottom of the syringe (syringe is empty) or if heparin is pumped into a high pressure. An over-pressure message is displayed on the front panel during this condition.

The operator enters the desired heparin delivery rate via the CRT touch screen. The host controller (80XX microprocessor) converts this information to a stepper motor step rate and sends it to the blood pump controller (8040 microprocessor) on the Blood Pump Controller board. At the same time the host sends a heparin pump overspeed alarm limit to the IO controller on the IO Controller board. The alarm limit is set to 5% over the desired rate. The IO controller monitors the heparin motor step signal period and compares this to the alarm limit. An overspeed condition exists when the period is less than the alarm limit, in which case the IO controller sends an alarm to the host and disables the heparin pump motor driver.

The operator may also request a bolus to be infused at a high speed rate via the CRT touch screen. When this occurs the host sends the total number of motor steps to be taken at the high rate to both the Blood Pump Controller and the IO controller. The controller sets the overspeed alarm if an excessive number of high speed steps occur.

The high step rate mode also results when the rack and pinion have not meshed correctly. This occurs if the heparin pump is on and an end of stroke is detected after the front panel syringe holder arm has just been engaged. During this condition the heparin motor runs at the high rate until the rack and pinion mesh. The maximum time it is allowed to run in this mode is 1.7 seconds. To prevent this mode from triggering an overspeed alarm, the high speed alarm limit in the IO controller is set to an appropriate value each time the syringe holder arm is disengaged.

Test Data

Flow Accuracy

Motor Speed Accuracy

The accuracy of the stepper motor controller was tested by measuring the distance the heparin pump rack moved with a dial indicator in a given amount of time. This test was done when the motor speed was in the normal speed range and when it was in the high speed bolus mode. The heparin pump variables were set using the UCCOM1A test program that reads and writes to controller variables.

In the bolus mode, the controller receives the total number of motor steps to be taken in the variable, BOLSTEP. The motor is stepped

once every 4 milliseconds. BOLSTEP was set to the value calculated to move the rack one inch:

Motor Steps/Inch = steps/motor r v * gear ratio * shaft r v/in
= 48 * 300 * 0.5991716
= 8628.07
= ~8628

The bolus speed test was run with 10 pound and 20 pound loads on the rack, as well as with no load. The 10 pound load represents the maximum the heparin pump is required to drive as defined by design specification. At greater loads, the heparin pump mechanism is designed to disengage the rack and pinion. The 20 pound load test was done by defeating this design feature. Ten tests were run at each load. A summary of this data is given below.

Bolus Speed Test

Distance Traveled @	0 lb	10 lb	20 lb
Average	0.9993	0.9999	0.9958
Std Dev	0.0026	0.0020	0.0023
% Avg.Error	0.07	0.01	0.42

In addition to validating the accuracy of the stepper motor controller, the above data also shows the motor delivers the torque required to move the rack with a 20 pound load.

In the normal speed mode, the controller receives a number in the HDCOUNT variable which it interprets as the number of 4 millisecond counts between motor steps. This determines the motor speed. The relationship between heparin rate and HDCOUNT is:

HDCOUNT = (syringe area cm²) * (294.39E-6 cm/step) * (counts/ (3600 sec/h) * (1/.004 count/sec) * step) (1/desired rate h/mL)

HDCOUNT correlates to speed as follows:
Speed(in/h) = (1/HDCOUNT step/count) * (1/.004 count/sec) * (1/8628 in/steps) * (3600 sec/h)

The above test was repeated at normal speeds representing 0.5 mL/h, 1.0 mL/h, and 5.5 mL/h flow rates assuming a 12 cc Monoject syringe (area = 1.936 cm2). This was done at no load only. The motor was allowed to run for over one hour.

Normal Rate Speed Test

Rate (mL/h)	HDCOUNT	Calculated speed (in/h)	Measured Error	Percent
0.5	1026	0.1017	0.1018	.10
1.0	513	0.2034	0.2049	.74
5.5	94	1.1185	1.1088	−.86

Heparin Flow Vs Pump Speed

To validate the relationship between motor speed as determined by the HDCOUNT variable and heparin flow rate in mL/h, volumetric testing was done. This test was done on the System 1000 monitoring machine #1 using a 12 cc Monoject syringe. The heparin rate was set via the CRT touch panel and the fluid pumped into a pre-weighed covered flask. Two tests were done at 0.5 mL/h and one at 5.5 mL/h. Each test was one hour long. Prior to each test, a bolus was delivered to remove any slack in the mechanism. The results are below.

Volume Accuracy Test

Rate	Volume	Percent
(mL/h)	(mL/h)	Error
0.5	0.489	2.2
0.5	0.496	0.8
5.5	5.45	0.9

Also, the amount of fluid delivered by a 1 cc bolus was measured. Thirty four bolus runs delivered an average bolus volume of 0.989 mL with the worst case volume of 0.973 mL. This is an average error of 1.1% and a worse case error of 2.7%.

Power Derating

The power derating of the heparin pump motor drive circuitry located on the Blood Pump Power board was determined with the motor operating at the maximum bolus speed with each drive transistor providing a 125 Hz output signal.

The following is the data for the zener diode, 1N4746.

1N4746

Power	0.216 W
Ambient Temp	26.1°C
Lead Temperature	52.2°C
Junction to Lead	21.6°C
Junction to Ambient Rise	47.7°C
Max Tj	200°C
Max Ta	60°C
Derating	65.9%

The drive for the heparin pump motor consists of four darlington transistors in two ULN2003A ICs. There are 7 transistors per IC. The maximum continuous power specified for one IC is 833mW at 60°C.

Transistor		Use	Power
U7	U3		(mW)
A	D	Heparin motor drive, 50% duty cycle	119
B	E	Heparin motor drive, 50% duty cycle	119
C	F	Level adjust drive	30
D		Level adjust drive	30
E	C	Heparin signal inverter, 50% duty cycle	2
F	B	Heparin disable buffer	4
	A	Shutdown buffer	23
	G	Heparin disable LED drive	8
G		Not used	

To determine the power derating of the ULN2003 all devices within the IC and their typical usage must be considered. Typically the level adjust motor is turned on for less than 30 seconds at a time. This is not long enough for its power dissipation to add to a stable thermal equilibrium. The heparin disable buffer, heparin disable LED drive, and the shutdown buffer are all off during normal machine operation. Therefore, only the the power dissipation of the heparin motor drive and heparin signal inverter transistors contribute to the continuous power disipation of the package.

Typical Motor Driver (ULN2003) Power

Total Power	% D rated
240 mW	71

It is worth noting that the energy dissipated in the switching time of the heparin drive transistor is 0.8 mJ. This is 42% of the total energy dissipated when running at 125 Hz. However, a more typical sustained running frequency is 0.157 Hz which correlates to a 5.5 mL/h delivery rate with a 10 cc syringe. At this slow step rate the energy dissipated in the switching time drops to less than 1% of the total energy dissipated.

The current limit resistors, 68 ohm 5 W, dissipate 1.64 W. This gives a power derating of 67%.

Overspeed Alarm Function

During normal speed operation the IO controller monitors the heparin motor step rate. After 40 heparin motor steps, it checks the time elapsed and compares this to the alarm limit, HP_P_MIN. If the time elapsed is less than the alarm limit, the motor is stepping faster than desired and an overspeed alarm is signaled.

To verify the alarm functioned, the heparin pump was turned on via the front panel of the monitoring machine #1. The alarm limit was then altered to a number 6% greater than was set by the host. (This was done using a separate program, UCCOM1A, that reads and writes to controller variables.) It was verified that the heparin overspeed alarm was activated.

During high speed operation, the total number of motor steps is monitored by the IO controller. When a bolus is requested, the negative of the required number of steps (plus some tolerance) is put in the IO alarm limit variable, H_SPD_CNTR. If this number of high speed steps is exceeded, the overspeed alarm is set.

To verify this alarm functions, the total number of allowed high speed steps in the IO variable, H_SPD_CNTR, was set to −5 using the UCCOM1A program on the integration machine. Then a bolus was begun. It was verified that the overspeed alarm resulted.

Summary

The errors of the heparin motor controller in bolus and normal speed modes were a maximum of 0.42% and 0.86% respectively. These errors increased to a maximum of 2.7% and 2.2% respectively in the volumetric testing. This increase in error can be attributed to the error inherent in the mechanical fixture and variation in syringe size.

Data was presented showing that the heparin motor drive surpassed the design goal of 50% power derating. The zener diode is derated by 65.9%, the ULN2003 darlington transistor array ICs is 71% derated, and the current limit resistor is 67% derated.

The heparin pump overspeed alarm was tested and found functional in both the normal and bolus speed modes.

Ambient Temperature Control

Description

The purpose of the cabinet cooling system is to keep the internal temperature of the cabinet lower than the 50°C maximum temperature at which the electronic components are guaranteed to operate. A fan is located at the base of the cabinet and exhausts the warm cabinet air. An intake vent for the ambient room temperature is located below the CRT on the back of the machine.

The cabinet cooling system consists of the following major components:
Description
Location

Cabinet Fan*	Base of cabinet
Blood Pump Temperature IC	Blood Pump Power Bd
Misc IO Temperature IC	Misc IO Electronics Power Bd
Software Fan Control	Host controller
Cabinet Fan Drive	Blood Pump Power Bd

The two LM35DZ temperature ICs are located on the Blood Pump and Misc IO Electronics power boards. This IC outputs a voltage linear with temperature in °C (10.0 mV/°C). These temperature readings are input to the fan control software.

The fan control software always responds to the higher of the two temperatures. The control temperatures at which the fan turns on or off are set in the host software. The control temperatures are set as follows: at 46°C it turns on the fan in the low speed mode and at 48°C it turns on the fan in the high speed mode. There is a 2°C of hysteresis at these threshold temperatures; i.e., the fan returns to low speed at 46°C and turns off at 44°C. In addition, at 60°C a cabinet temperature alarm occurs that results in the machine shutdown state.

The fan power driver located on the Blood Pump Power board provides an unfiltered pulse width modulated signal at a frequency of approximately 30 KHz to the fan motor. Testing was done using Rev Z10 of the Blood Pump Power board.

Data

Fan Cooling Capability

To determine the cooling capability of the fan, the machine was allowed to stabilize at its maximum internal temperature without the fan on. The cabinet was closed, the blood pump was on, and the dialysate flow rate was set to 1000 mL/min. After the cabinet temperature had stabilized the fan was turned on. The temperatures from the temperature ICs on the IO and Blood Pump power boards were sampled every minute and are shown on the graphs below.

The accuracy of this data is dependent on the accuracy of the LM35DC temperature IC and the resolution of the D/A conversion. The accuracy of the LM35DZ is ±2°C over the full temperature range of −55 to 150°C.

The resolution of the D/A converter is as follows:

Blood Pump IC:	5 V/255 = 19.6 mV
	19.6 mV * (1°C/10 mV) = 1.96°C
Misc IO IC:	5 V/1023 = 4.9 mV
	4.9 mV * (1°C/ 10mV) = 0.49°C

This resolution adds a negative error only as a monotonic D/A converter is used. The temperature reading of the Blood Pump IC is within −4 to +2°C of actual and the reading of the Misc IO IC is within −2.5 to +2 °C.

The fan was run at four separate speeds (motor voltages) by setting the FAN_RATE variable to 180, 195, 210 and 255. These FAN_RATE variables correspond to 20 V, 22 V, 25 V, and 26 V applied to the fan. The graphs below show the results.

SATRN COOLDOWN RATE VS. FAN SPEED
FAN SPEED = 180
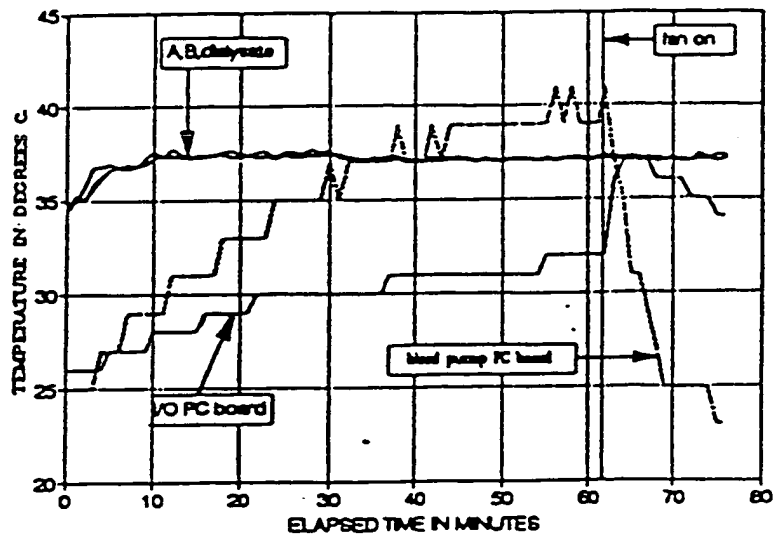
SATRN COOLDOWN RATE VS. FAN SPEED
FAN SPEED = 195
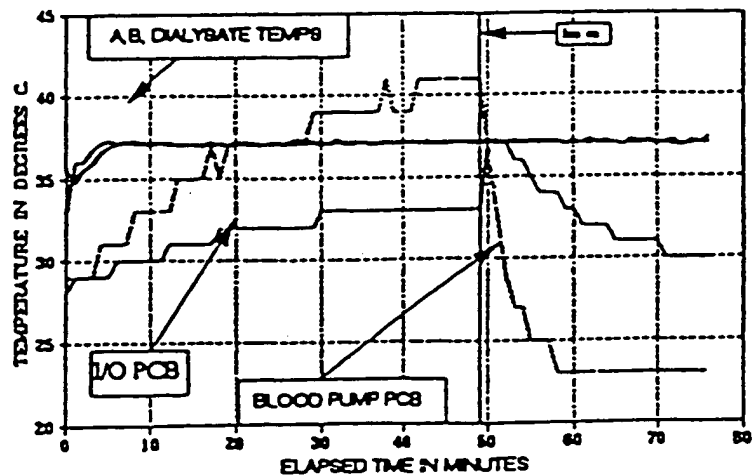
SATRN COOLDOWN RATE VS. FAN SPEED
FAN SPEED = 255
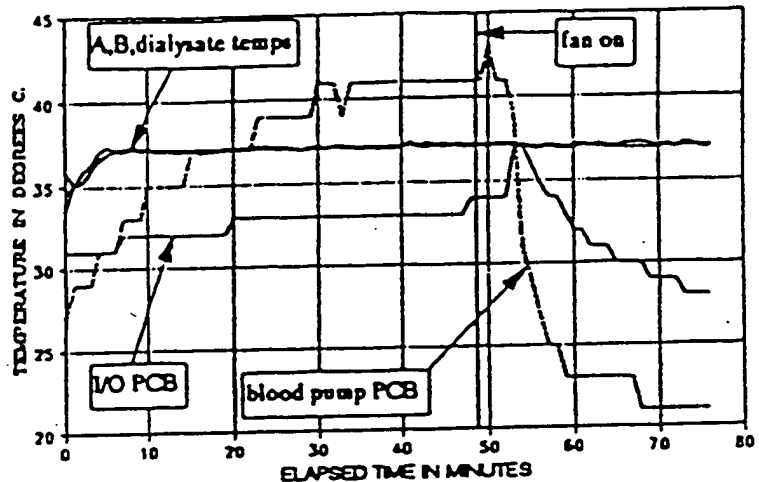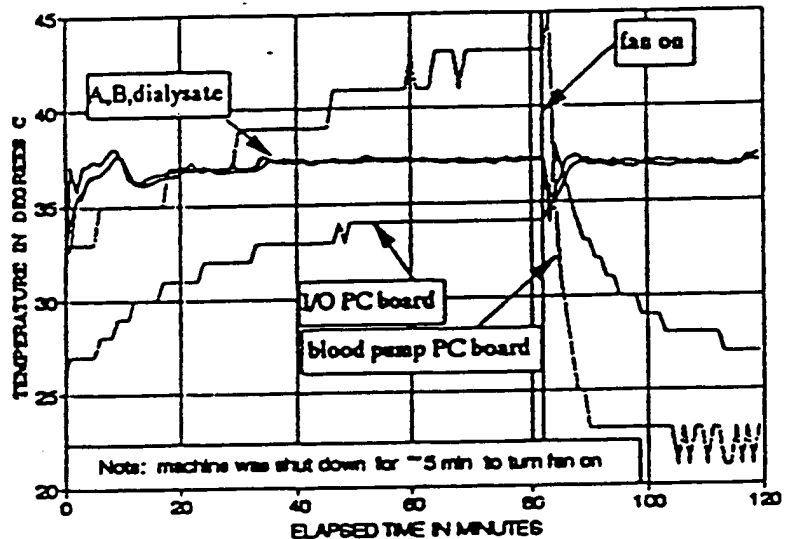
The temperature IC on the Blood Pump Power board reports the higher temperature prior to the fan being turned on. When the fan turns on, the temperature at the Blood Pump Power board decreases rapidly, the temperature at the Misc. IO Power board increases momentarily and then decreases gradually. This is understandable when the location of these boards is considered. The Blood Pump Power board is located just below the CRT, perpendicular to the front panel, close to the air intake vent. The Misc IO Electronics Power board is mounted to the bottom of the front panel. Prior to fan turn on, the temperature at the Blood Pump Power board is greater than at the Misc IO Power board because it is higher, and hot air rises. When the fan turns on, the temperature at the Blood Pump Power board decreases rapidly as it is close the intake vent. The temperature at the Misc IO Power board increases initially as the warm air from the top part of the cabinet is drawn past on its way to

the exhaust at the base of the machine. The temperature at the Misc IO Power board decreases more gradually as there is less air flow around this board due to the location of other components.

The amount the cabinet temperature rises above ambient temperature without the fan on may be determined by the graphs. The assumption is made that the stabilized temperature at the blood pump power board with the fan on is the ambient temperature. This data indicates a maximum temperature rise of 24°C.

For each graph the Cool Down Rate is calculated. This is defined as:

$$\text{Cool Down Rate} = \frac{\text{Max Temp - Min Temp}}{\text{Time Min Temp Reached - Fan On Time}}$$

Fan Rate	Blood Pump Power board	Misc IO Power board
180	(41 - 23)/(76 - 62) = 1.28°C / min	(37 - 34)/(75 - 62) = 0.23°C / min
195	(41 - 23)/(58 - 49) = 2.0°C / min	(37 - 30)/(71 - 49) = 0.32°C / min
210	(43 - 23)/(59 - 49) = 2.0°C / min	(37 - 28)/(73 - 49) = 0.37°C / min
255	(45 - 23)/(90 - 82) = 2.75°C / min	(38 - 27)/(112 - 82) = 0.37°C / min

The cool down rate is not linear as it is a function of the air convection currents within the cabinet.

Another important factor in considering the speed at which to operate the fan besides the cooling effectiveness is the noise level. The following are the subjective impressions of the noise level at each fan rate made by the technician who ran the test. "At 255, the sound of the fan was the loudest sound produced by the machine. The sound produced by the fan was markedly less at 210, though still quite noticeable. At 195 the fan was all but silent, and at 180 it could not be heard above the other machine sounds."

The data from the graph with the fan rate set to 255 was compared to temperature data obtained from thermocouples placed throughout the cabinet taken simultaneously. The Blood Pump Power board maximum and minimum temperature is compared to the temperature recorded by a thermocouple located on the top right corner of the Mother board. The Misc IO Power board maximum and minimum temperature is compared to the temperature of the thermal couple located at the top of the switching power supply board. The results are below.

	Thermo-couple	Board Temp IC	
Blood Pump	38	45	Prior to fan on
Temperature	23	23	Fan on
Misc IO	46	38	Prior to fan on
Temperature	27	27	Fan n

The readings with the fan on are identical. However, the temperatures just prior to fan turn on vary considerably. This

highlights the fact that convection air currents are a major factor and slight differences in location are significant.

In the base of the machine is located the heater solid state relay. To maintain its desired 50% power derating at 120 V nominal line voltage, the cabinet temperature must be 50°C or less. Therefore, the temperature at the base of the machine is of particular concern. A temperature sensor located above the solid state relay showed that the temperature initially increased approximately 8°C at fan turn n before decreasing slowly. This occured at all fan speeds.

Summary

Data was collected to show the fan's effectiveness at cooling the cabinet temperature running at four different speeds. The data showed that all speeds were effective at cooling the temperature at the Blood Pump Power board and the IO Electronics Power board.

This data also showed a maximum ambient to cabinet temperature difference of 24°C. This indicates that at ambient temperature of 22°C or greater the fan will turn on at the low speed rate.

The software fan control was tested and it was verified that the fan turned on and off at the preset rates and at the preset temperatures.

Level Adjust

Description

The level adjust system allows the operator to change the blood level in the arterial, veneous, and expansion drip chambers. Level up and level down buttons exist for each drip chamber. When a button is pressed, a valve selects that drip chamber and power is supplied to the motor such that the pump head of a peristaltic pump rotates to apply a positive or negetive pressure to the drip chamber. The control logic only accepts one button press at a time.

The level adjust motor may be driven in the forward or reverse direction. A direction signal along with a pulse width modulated motor rate signal controls two bipolar half bridge motor drivers. Both half bridge motor drivers receive the same motor rate signal, while the motor direction signal is high at one and low at the other to determine the direction the motor runs. The half bridge drivers provide a 24 V pulse width modulated drive voltage of approximately 30 KHz to the motor.

Test Data

Power Derating

The power derating of the level adjust motor drive circuitry located on the Blood Pump Power board (rev Z10) was determined under the worse case condition of the pump head being held in position so that it would not turn. Also, power derating was determined at a typical load of pumping against +400 mmHg pressure. The motor voltage was 12 V.

Data for both half bridge motor drivers (UDN2935Z) is shown below. The driver sinking current is defined as the one with the input at pin 2 high. The driver sourcing current has the input at pin 2 low. One half bridge driver was mounted on each side of the AAVID 530122 heatsink. The table below shows the data.

Sinking Current Motor Driver

	Pump Stopped	+400mmHg Pressure
Power	1.37 W	0.24 W
Ambi nt T mp	26°C	26°C
Case Temperature	46°C	39°C
Junction to Case Rise*	5.5°C	1°C
Junction to Ambient Rise	25.5°C	14°C
Max Tj	150°C	150°C
Max Ta	60°C	60°C
Derating	72%	84%

Sourcing Current Motor Driver

	Pump Stopped
Power	0.42 W
Ambient Temp	22.6°C
Case Temperature	44.2°C
Junction to Case Rise*	1.7°C
Junction to Ambient Rise	23.3°C
Max Tj	150°C
Max Ta	60°C
Derating	74%

* $Ojc = 4°C / W$

Flow Rate Vs Pressure

The flow rate the level adjust system is able to deliver when pumping air against a +600 mmHg pressure and exhausting air from a −300 mmHg pressure was measured. These pressure values were selected as the maximum pressures expected to be used in a clinical situation. The time to empty/fill 25 mL of water with the level adjust motor at 12 V and 15 V was measured. (A D/A value of 146 was used to set the motor voltage at 12 V and 168 to set the motor voltage at 15 V.)

	12 V	15 V
+600mmHg	1.24 mL/sec	1.59 mL/sec
−300mmHg	0.53 mL/sec	0.74 mL/sec

In addition, the motor pump head speed was measured at 57 rpm with 12 volts applied to the motor and at 75 rpm with 15 volts applied to the motor.

Summary

The power derating of the UDN2935Z half bridge motor drivers that power the level adjust motor was examined. Under the unlikely condition that the motor is stalled the sinking driver was 72% derated and the sourcing driver was 74% derated. This exceeds the design goal of 50% derating.

Data was presented that showed the slowest flow rate occurred when exhausting air (raising the fluid level) at a pressure of −300 mmHg. Typical drip chambers range in volume from 8 mL to 18 mL. At 0.53 mL/sec it would take 34 seconds to fill the 18 mL drip chamber.

Blood Pump Controller

Description

The purpose of the blood pump controller is to supply power to the blood pump motor such that the pump head will turn and pump at a rate selected by the operator.

The blood pump controller system consists of the following major components:

Description	Location
User paramet r entry	Host controller
Software Speed Error Control	Bld Pmp Controller
Hardware Speed Error Control	BP Power Board
Optical speed sensor	On motor shaft
Motor Power Driver Circuitry	BP Power Board

The operator enters the desired blood pump rate information on the CRT touch panel. The host controller (80XX microprocessor) converts this information to the appropriate motor rate which it then sends to the Blood Pump controller (8040) on the Blood Pump Controller board. The 8040 controller converts the motor rate information to an analog level, which is fed to a motor speed control IC (LM2917-8) on the Blood Pump Power board.

An optical speed sensor is mounted on the rear saft of the blood pump motor, with an LED being positioned on one side of the shaft, and a photo transistor on the opposite side. The shaft has two holes drilled through it, with each hole being perpendicular to the shaft and to each other. This results in four optical pulses received per shaft revolution.

This tachometer signal is monitored by both the LM2917-8 and the 8040 controller. The LM2917-8 provides quick responding speed control by comparing the motor speed with the desired speed information from the 8040. The result of this comparison is an error signal which provides an input to the motor power driver circuit.

The motor power driver provides a +24V pulse width modulated drive to the motor at a frequency of approximately 30 KHz. This drive is current limit protected, to prevent damage in the event of a stalled motor.

The 8040 compares the tachometer motor speed information with the desired speed commanded by the 80XX and corrects the level provided to the LM2917-8 accordingly. In this way the 8040 guarantees the ultimate accuracy of the pump, with the LM2917-8 circuit not requiring any calibration. In addition, the 8040 can monitor for control problems, such as under speed or over speed, which may result from failures in the LM2917-8 or motor drive circuitry.

The 8040 also monitors the motor speed independent of the tachometer signal using the motor's back EMF. Periodically (every 0.5 second) the motor drive is turned off for approximately 6 msec and th voltage at the motor terminals is measured. Though this does not result in as precise an indication as the tachometer signal, gross failures can be determined, such as when the tachometer signal is lost.

Test Data

Flow Accuracy

Motor Speed Accuracy

The accuracy of the motor controller was tested both under a heavy tubing load (occluded water filled T8 tubing) and under no load. The speed of the pump head was independently measured using an event

counter connected to a reed switch, with a magnet mounted to the pump head, such that the reed switch was activated once per pump head revolution. This measured speed was compared with the expected pump speed, which is bas d on the value of the blood pump controller's DES_CNT1 variable. DES_CNT1 is set by the 80XX host to control the pump rate. The blood pump controller interprets DES_CNT1 as the number of motor tachometer pulses that should occur in 0.5 second, times 16. The relationship between pump head RPM and DES_CNT1 is

RPM = (DES_CNT1*2/16) pulses/sec

60 sec/min /

4 pulses/mtr shaft rev /

18.93 mtr shaft rev/pump shaft rev

RPM = DES_CNT1 / 10.096

The following are the test results:

DES_CNT1	Expected RPM	Actual No Load	Error No Load	Actual Loaded	Error Loaded
50	4.9525	4.9565	0.08%	4.9565	0.08%
100	9.9049	9.9135	0.09%	9.9094	0.05%
530	52.4960	52.5363	0.08%	52.5118	0.03%
1100	108.9540	109.0118	0.05%	109.0516	0.09%
1400	138.6688	138.7748	0.08%	138.7179	0.04%

The 80XX host converts the blood flow rate entered by the operator (Q) to a DES_CNT1 value using the following nominal relationship:

DES_CNT1 =   Q mL/min /
5.9 mL/pump rev
18.93 mtr shaft rev/pump shaft rev /
60 sec/min
4 tach pulses/mtr shaft rev
0.5 sec/sample period
16 Des_cnts/tach pulse

=   1.711 Q

This relationship assumes .25 inch ID blood tubing. The actual expression includes a calibration term which allows the calculated DES_CNT1 to be incremented or decremented in 1% steps.

This conversion performed by the host was verified by setting the blood flow rate from the front panel to various levels, after which the Blood Pump controller's 8040 was interrogated to determine the current value of DES_CNT1. The following results were obtained:

Desired Blood Flow	Expected DES_CNT1	Actual DES_CNT1
100	171	171
200	342	342
300	513	513
400	684	684
500	855	855
600	1026	1026
700	1197	1197

Blood Flow Vs Pump Speed

The relationship between the pump speed and the pumped fluid flow rate was determined by measuring the amount of water pumped over

a measured period of time. The following shows the results with 0.25 inch ID tubing:

Pump Speed RPM	Flow Rate mL/min	mL/rev
10	60.0	6.0
20	115.0	5.8
30	169.0	5.6
40	225.0	5.6
50	282.5	5.7
60	340.0	5.7
70	410.0	5.9
80	465.0	5.8
90	523.3	5.8
100	585.0	5.8
110	640.0	5.8
120	704.0	5.9
130	760.0	5.8

The average of the mL/rev column is 5.8.

Drive Torque

Torque Requirements

To gain an estimate of the worst case load requirements for the blood pump, the pump was loaded with T8 tubing, which was filled with water and occluded. The motor current was then measured while running at 124 RPM (equivalent to 720 mL/min with 0.25 inch tubing). The resulting current averaged 2.1 A.

Dynamometer tests showed that a motor current of 2.0 A while running at 110 RPM is approximately equal to a motor load of 120 oz-in.

Drive Capability

Data was taken to determine the drive capability of the blood pump by connecting the pump shaft to a dynamometer, and then at various

Blood Pump Torque Vs Speed
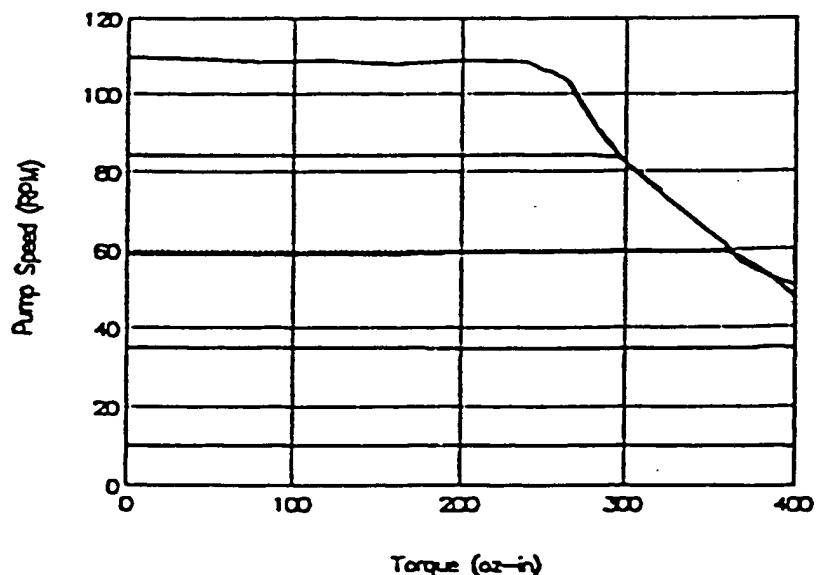
no load pump speeds increasing the mechanical load to 400 ounce
inches. The results show that the pump can maintain a speed of up to
50 RPM under a 400 oz-in load. For speeds greater than 50 RPM, the
maximum torque decreases linearly down to 240 oz-in at 110 RPM.
Though the motor wasn't tested above 110 RPM, extrapolation of the
data indicates that it will drive 200 oz-in at a speed of 120 RPM. The
torque-speed limit is a result of the motor driver's current limit
function, which protects the circuitry from damage under excessive
loads.

Power Derating

Drive Transistor and Catch Diode

The power derating of the blood pump driver circuitry located on the
Blood Pump Power board (revision Z10) was determined under the
worst case condition of the pump head being secured so that it would
not turn. This resulted in the driver circuitry being in continuous
current limit with a motor current of 6.2 A. The test was performed
originally with the MTP3055E driver transistor (Q5) and MUR805
diode (D1) mounted to a common heat sink (CD Medical part number
M-1991-00-00) with the following results.

	MTP3055E	MUR805
Power	4.7 W	3.4 W
Case Rise	45°C	48°C
Junction Rise	60°C	58°C
Max Tj	150°C	175°C
Max Ta	60°C	60°C
Derating	33%	50%

Motor Stalled/ Single Heat Sink

It is acknowledged that the lower case rise of the MTP3055E is
inconsistent with its higher power dissipation. It is suspected that
this is a result of the difficulty of measuring the transistor's on
voltage accurately. It is further suspected that the actual
MTP3055E's power dissipation is closer to the MUR805's dissipation
of 3.4 W, since the case temperature rises are similar. This analysis
will continue to utilize the 4.7 W dissipation however, since this is
will result in a more conservative derating.

Because of the low derating of the MTP3055E, the heat sink
configuration was changed so that the MTP3055E and and MUR805
were mounted to two separate Aavid E5304B heat sinks. Actually
two MTP3055E transistors were mounted to one, and two MUR805
diodes were mounted to the other, but since the additional
components are for the second blood pump, they would not be
expected to contribute any power during the primary blood pump
operation. The following summarizes the derating data using the two
heat sinks.

	MTP3055E	MUR805
Power	4.7 W	3.4 W
Case Rise	35°C	35°C
Junction Rise	49°C	45°C
Max Tj	150°C	175 °C
Max Ta	60°C	60°C
Derating	45%	61%

Motor Stalled/ Double Heat Sink

The design goal was to maintain a 50% or greater derating for all power components. As can be seen, the MTP3055E is only derated 45%. However this is a very conservative figure, since the test was done during a motor stall condition, which is unrealistic during normal operation. Testing of the original single heat sink configuration, with the pump driving a constant 360 oz-in load, has shown that the MTP3055E case rise was 24°C compared to 43°C during a stall. This implies that the transistor was only dissipating 24/43 = 56% of the stall power. Applying this information to the double heat sink data results in the following:

	MTP3055E
Power	2.6 W
Case Rise	20°C
Junction Rise	27°C
Max Tj	150°C
Max Ta	60°C
Derating	70%

360 oz-in Load/Double Heat Sink
(Calculated Data)

The 360 oz-in load is still a conservative estimate when considering that a very heavy tubing load is approximately equal to 120 oz-in (see Torque Requirements in this report).

Shutdown Transistor

The TIP105 shutdown transistor on the Blood Pump Power board (Q8) supplies +24 V current to the following loads:

- blood pump motor
- level adjust motor
- heparin pump motor

As a result, its power dissipation and temperature rise was accessed during the following worst case condition:

- blood pump motor on and stalled (current limit)
- level adjust motor on and stalled
- heparin pump motor on but not stepping

From photos taken of TIP105's voltage and current under this condition, the power dissipation is estimated to be 0.8 V * 1 A = 0.8 W. Under this same condition the transistor case temperature rise was 50 - 24 = 26°C. The junction to case temperature rise is 1.56°C/W * 0.8W = 1.2°C, resulting in a total junction temperature rise of 27.2°C. The following is the derating information.

	TIP105
Power	0.8W
Case Rise	26°C
Junction Rise	27.2°C
Max Tj	150°C
Max Ta	60°C
Derating	70%

Worst Case Shutdown Transistor Derating

Summary

Data was presented showing that the blood pump controller maintains the pump speed within 0.1% of the expected rate. Actual fluid pumping accuracy tests were not performed because of the dependency on the tubing tolerances. Accuracy with any particular blood line set can be optimized through the blood pump calibration.

Blood pump drive requirements were conservatively determined to be 120 oz-in at a speed of 120 RPM (700 mL/min with 0.25-inch ID tubing). Test results indicate that the pump is capable of driving a 200 oz-in load at a speed of 120 RPM.

The power derating of the blood pump motor drive components were examined, which consist of drive transistor Q5 (MTP3055E) and the catch diode D1 (MUR805). Under the extreme condition of a stalled motor, the transistor was 45% derated and the diode was 61% derated. Even though the transistor derating did not meet the design goal of 50%, its derating was 70% under a still conservative load condition of 360 oz-in.

Power derating of the Q8 shutdown transistor was also determined. This transistor conducts the +24V current to the blood pump motor, level adjust motor, and heparin pump motor. Under the extreme condition of a stalled blood pump and level adjust motor, the derating was 70%.

Extracorporeal Blood Pressure Measurement

Description

The extracorporeal blood pressure measurements include the venous, arterial and expansion chamber (for Single Needle treatment) pressures. All three measurement systems include identical hardware. Each pressure is sensed by a SenSym SCX15 pressure transducer mounted to the Blood Pump Power board. Each transducer is connected to a differential amplifier designed to provide a measurement range from –400 to +600 mmHg. The output of each amplifier drives an A/D input channel of the Blood Pump Control system, at which point it is converted to a 10 bit digital value. The calibration of the each pressure input is handled entirely in software, requiring that the design of each amplifier guarantee that its output remain within the A/D input range of 0 to +5 V over the input pressure range and over all component tolerances.

Since all three pressure systems are identical, qualification testing was only performed on the venous system.

Test Data

The venous pressure system was tested by applying a pressure to the venous pressure transducer, and measuring the pressure independently using a mercury manometer. The input pressure was stepped from +650 to –450 mmHg in 50 mmHg steps. For each pressure the differential amplifier output voltage was recorded, along with the converted digital value which was communicated from the Blood Pump controller board's 8040 microcontroller.

Over the applied pressure range the amplifier output ranged from 0.603 to 4.09 volts, well within the required 0 to 5 V range. A linear

regression of the output voltage provides the following relationship between pressure and voltage:

$$V = .003167 * P + 2.0301$$

with an r.SUPER2.SUPER value of 0.999988. This expression was used in reverse to calculate P from the measured V values, and the difference between these calculated pressures and the measured pressures were plotted as shown.

Pressure Amp Output Accuracy
(Calculated - Measured)
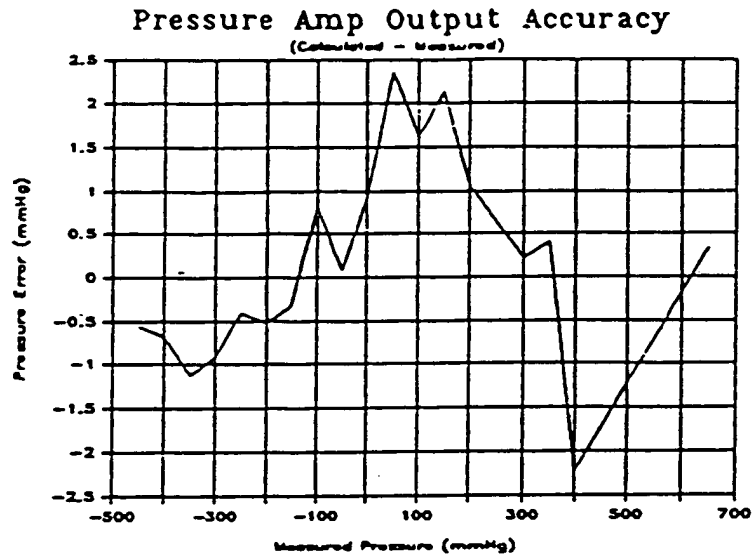
The A/D values can be compared with the measured voltages using the following expression:

$$A/D \text{ value} = V/5 * 1023$$

By using this expression in reverse to calculate A/D input voltages, and then subtracting the measured voltages, the plot resulted.

A/D Conversion Accuracy
(Calculated - Measured)
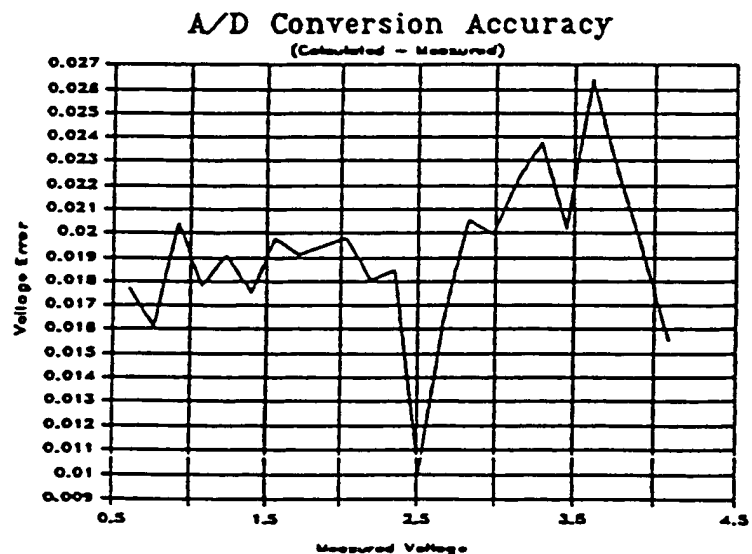
Mechanical Assemblies

Air Detector

The function of the air detector is to detect 10 microliter and greater volumes of air in the venous blood line. This specification is to be valid at blood flow rates up to 700 mL/min. The method of detecti n used is very similar to that used in the current 480 line of equipment. A two megaHertz continuous wave ultrasonic energy beam is passed through the blood tubing wall, through the blood, and then back through the tubing again. The signal is then picked up with an ultrasonic receiver, and passed along to the rest of the electronics. When an air bubble passes through the ultrasonic beam it reflects the waves impinging on it, therefore creating a 'shadow' that the receiver sees as a decrease in received energy.

The System 1000 air detector uses a rigid acrylic bumper. This eliminates the wear related problems experienced with elastomeric bumpers. The bumpers are also set a fixed distance apart. The idea behind the fixed bumpers was that if the moving parts of a spring loaded system could be removed, and still maintain good detector operation, a simpler and more reliable system would be made. The only problem found in using the fixed bumpers was an increase in the sensitivity of the detector to blood tubing movements. This problem was greatly reduced by making a hinged cover that securely holds the blood tubing in between the two bumpers.

Line Clamp

Design

The function of the line clamp is to stop fluid flow in the blood tubing. The clamping is done via a spring loaded plunger that pinches the blood tubing closed. To open the line clamp the plunger is pushed open and held open with an electric solenoid. With this design, even in the event of an electrical power outage, the spring will clamp the blood tubing and stop fluid flow.

The spring for this line clamp was designed with fatigue as it's prominent mode of operation. The final design produces only 35350 psi of shear stress at it's minimum operating height. This stress level is only 13.7% of the ultimate tensile strength of the wire, therefore ensuring a cyclic lifetime of over 1 million cycles. With a conservative estimate of 40 cycles per dialysis treatment, or 262000 cycles for a 7 year life, the spring far exceeds the required life, by design.

The high temperature problems of some solenoid actuated line clamps were fixed by the electrical design team. The problem of conducting heat to external parts was reduced in this design by limiting the heat conduction paths to user accessible parts. The combination of these two solutions has resulted in line clamp that has a very minimal temperature rise when in operation.

Life Test Results

Two line clamp assemblies were set up in an automated test fixture that ran 24 hours a day. The purpose behind this test was to subject the line clamps to an extreme number of cycles and see how the design held up. The results after 470000 cycles were as follows:

- One of the occlusion springs force dropped 0.6 lbf ver the life of the test, while the other springs force stayed constant. The data on the spring that changed does show a changing force over the whole test, with the values going up and down. The other assembly was very consistent in its force during the test.

- One solenoid showed 0.001 inch wear on its internal bushing, with no wear exhibited on the shaft that runs through it.

- One occlusion plate bearing showed 0.002 inch of wear.

- The polyurethane bumper/plug only exhibited a maximum of 0.003 inch of compression and wear.

- The occlusion gap of the devices decreased by 0.011 inch on one unit, and 0.003 inch on the other.

- A pressurized blood tubing was placed in the line clamp to test the life of the tubing itself. With 16 psig pressure in the line, a total of 3121 cycles were recorded before a leak was detected.

All of the above results show that this device is an extremely stable and reliable line clamp. The 470000 cycles calculated out to 25 years of life at 40 cycles per dialysis treatment. The 3000 plus cycles that the piece of blood tubing lasted before leaking is approximately 75 times the required life.

Qualification Test Results

The line clamp was tested to determine its ability to occlude against pressure, and its ability to maintain a clamped state. The blood tubing was pressurized to 30 psig and the clamp was able to shut off the flow. The pressure was then increased to 35 psig with the clamp still closed, and no leaks were noted. The method used to determine whether the tubing was occluded or not, was based on using the conductivity of the salt water in the tubing. The conductivity went to zero for a fully occluded tubing, but one case was noted where this didn't occur. This case occurred when the blood tubing was located near the gap that is between the clamp block and the occlusion plate. The leak that occurred was on an ionic scale though, as compared to a fluid leak.

The line clamp occlusion time was checked to ensure that an air bubble will be stopped before reaching the line clamp. The maximum time to occlude the blood tubing was 32.6 milliseconds. This time is in agreement with previous measurements taken on the life test line clamps.

The ability to occlude against 30 psig (1551 mmHg.) is over double the allowable venous pressure of 600 mmHg.

The calculated occlusion time necessary to stop a bubble at a blo d flow rate of 700 mL/min is 70 milliseconds. The measured time is less than half of this value, therefore the bubbles will be stopped before they reach the line clamp.

Level Adjusters

The function f the level adjuster assembly is to provide positive and negative pressure to the arterial and ven us drip chambers in order to adjust the levels of blo d in the extracorporeal blood path. It is

composed of a peristaltic pump driven by a reversible gearmotor. The output of the pump is connected to a valve manifold which directs the pumping action to either of two paths. The assembly is made up mainly of off-the-shelf components, and development consisted largely of selecting components which had the desired characteristics.

Principal areas of development were as follows:

Pump Cartridges

The pumps used feature replaceable tubing cartridges. Tubing of different materials and sizes were compared. Considerations included adequate pumping rate at the desired maximum positive and negative pressures (+600 and −300 mmHg, respectively) and durability. We found that a 5 mm ID silicone tubing cartridge best fulfilled our needs. This cartridge provided a worst-case pumping rate (at −300 mmHg) of about 20 to 30 mL/min. Life testing showed that the tubing's expected life was well in excess of a recommended yearly replacement interval.

Gearmotor

The requirements here were adequate torque, reasonable power consumption, and sufficient durability. We tested three motors. A 12 Vdc worm-gear drive motor functioned well enough but had excessive current requirements. A 24-volt version of the same motor solved this problem but suffered from random stalling. The version that we settled on was a much smaller inline gearmotor. This motor fit into the machine better, and its noisier operation was not considered to be a handicap. Although nominally rated at 12 Vdc, the motor in th System 1000 is run on pulse-width modulated dc. The free-running voltage is about 20 volts, dropping to about 14 to 15 with the tubing cartridge loaded.

Valve Manifold

This consists of an aluminum block on which are mounted two or three miniature 2-way solenoid valves. The pump is connected to one port, and, depending on which valve is energized, the pumping action is routed to one of two or three outlet ports. Two very similar types of valves were tested. One of them (type A) proved to be prone to corrosion and jamming of the solenoid plunger. The other valve (type C) has so far been satisfactory.

Life Test Data

Most life testing was done using a relatively sophisticated fixture, controlled by a programmable controller, which caused each of two pumps under test to alternately pump to the required positive and negative pressures. The solenoid valves were alternately actuated as well. Periodically the pumping rate was measured by pumping against a constant positive or negative pressure and measuring the rate at which water was displaced in a graduated burette.

Heparin Pump

The function of the heparin pump is to precisely dispense heparin from a syringe to the extracorporeal blood lines. The linear motion used to move the syringe is produced by a simple rack and pinion

drive mechanism. The pinion is driven by a geared stepper motor which provides a positioning resolution of 0.000116 inch, before mechanical compliance.

The difficulties in loading the syringe were reduced in the new design. The syringe plunger is first attached to the rack gear, which is then slid upwards until the ears of the syringe stop against the cabinet. A spring loaded arm is then used to hold the syringe in place. This process allows the heparin pump mechanism to be positioned with the syringe in place.

A very simplified approach of clutching the motor to the rack gear was used. The gearbox output shaft is used to carry the main drive pinion gear. To disengage the pinion from the rack the motor carrier/mount is pivoted away from the rack gear, therefore disengaging the pinion from the rack. This approach has only one power transmission point external to the gearbox. This minimizes backlash in the drive system, and maximizes the power transmission efficiency of the drive. This same mechanism is also used to detect the end of the syringe stroke, or an overpressure state in the syringe. The natural force that tends to separate any two gears that are transmitting a force tries to pivot the motor carrier away from the rack. To keep the motor carrier in place during injection, a spring is used to hold it down. When the linear force on the rack gear exceeds approximately 10 lbf, the motor carrier pivots away from the rack and triggers an optical switch. This switch is then use to signal an overpressure/end-of-stroke condition.

A larger speed range was achieved by going to a numerically lower gear ratio in the gearbox. This change required the use of a larger motor, but the now expanded infusion rates allow for a bolus feature. The bolus feature not only allows a bolus to be given, but is an excellent method for removing any backlash in the drive system.

Life Test Results

One heparin pump assembly was set up in an automated test fixture. The main purpose behind this life test, besides trying to find any unexpected problems, was to verify the operation of the overpressure/end-of-stroke mode.

One problem that showed up early in the testing was the method of connecting the gearbox output shaft to the pinion drive shaft. A simple cross pin in the gearbox shaft mated into a cross slot in the pinion shaft, but the pin failed. This problem was easily solved by going to a long output shaft on the gearbox and installing the pinion gear onto it. This solution added very little cost to the gearbox, and in the process removed two parts from the assembly.

A problem did show up in the testing and operation of the overpressure/ end-of-stroke mode. The problem amounted to the high coefficient of friction at the pinion gear to rack gear interface. The friction force would build up to a point that the pinion tooth couldn't slide up the mating rack tooth. When this occurred the stepper m tor would either break the gearbox, or reverse its direction of rotation. Many different combinations of rack and pinion materials were tried until an acceptable solution was found. The results f the testing are

as follows, with the "number of cycles" equaling the number of cycles the mechanism work flawlessly.

Pinion Material	Rack Material	Number of Cycles
Stainless	Stainl ss	1000 to 1500
Aluminum	Stainless	32
Teflon/Aluminum	Stainless	778
Brass	Stainless	5875
Teflon/Stainless	Teflon/Stainless	12803*
Teflon/Stainless	Stainless	11843*

* Denotes that the test was stopped without a failure.

The Teflon/Aluminum is a hard anodize with Teflon impregnated into it, while the Teflon/Stainless is an electroless nickel plating and Teflon on the Stainless part.

The Teflon/Stainless pinion running on the Stainless rack was the combination of choice. With this combination the pump worked extremely well and with 11843 cycles, that works out to be approximately 19 years of life at four end-of-stroke cycles a day.

Qualification Test Results

The overpressure/end-of-stroke test was conducted using a 20 cc Monojet syringe at the 'bolus' rate, and at 5.5 mL/h.

Infusion Rate	Average Pressure	Standard Deviation
Bolus	28.3 psig	0.646 psig
5.5 mL/h	23.6 psig	0.418 psig

The calculated minimum shut off pressure for this syringe was 20.3 psig. The results of the 5.5 mL/h rate are an acceptable 16.3% ab ve the minimum. The higher pressures seen at the 'bolus' rate are due the greater speed at which the infusion takes place.

Blood Pump

The blood pump is a peristaltic pump. It consist of a rotor, a U shaped race which is built into the front of the machine and a tube segment which is part of the disposable blood tubing that is changed each treatment.

The rotor has two rollers mounted on pivoting arms. Each arm has a spring which forces the roller out toward the race, compressing the tubing. The outward movement is limited by a stop screw. This adjustment prevents large movements of the arm as it moves on and off the tubing.

The race is built into the machine. It is backed up by gussets to improve rigidity. The blood pump segment is made from clear PVC. Blood pump segments of 6, 7, and 8-mm ID and 1/4-inch ID can be accomodated.

Test Results

A test was done to determine the occlusion force of the roller on the tubing. The force required on the roller to just lift the pivot arm off the screw stop was 9.8 to 10 lbs.

A series of tests were done to characterize the performance of the blood pump over the specified range f inlet and outlet pressures and nominal pump rates. These tests were run with both the 0.25-inch ID and 8-mm ID pump segments.

The results showed that the pumping accuracies over the entire range of inlet and outlet pressures c mpared fav rably with previous blood pump designs.

Flow Equalizer

The flow equalizer has two primary functions, which are closely related. It controls an equal flow to and from the dialyzer as part of the ultrafiltration control system. It also controls overall flow through the machine as part of the proportioning system.

The flow equalizer works in conjunction with the UF removal flow meter to control ultrafiltration. If flows to and from the dialyzer are equal, any additional fluid that is withdrawn between the two flow control points must come from the blood through the dialyzer membrane. The UF removal flowmeter provides this function by accurate metering fluid out downstream of the dialyzer before it re-enters the flow equalizer. Depending on the UF removal rate the dialysate pressure automatically goes to a pressure sufficiently lower than the blood pressure in the dialyzer such that the prescribed UF removal flow is drawn through the dialyzer membrane.

The desired accuracy of this device is much better than any flow control device on the market. According to our design specification it should maintain flow to the dialyzer to within ±0.5 mL/min of flow returning from the dialyzer. With dialysate flows up to 1000 mL/min that is an accuracy of ±0.05%.

This accuracy is attainable by the nature of the device. It is a cavity separated into two chambers by a diaphragm and valved such that fluid entering one side displaces the same volume which exits the other side. There are two of these devices so that, in one, incoming fresh dialysate displaces an equal amount of fluid to the drain while, in the other cavity, fluid returning from the dialyzer displaces an equal volume of fluid going to the dialyzer. By switching these functions between the two cavities, a relatively constant flow can be maintained.

There are three categories of flow equalizer inaccuracies; air leak in or fluid leak out in the controlled volume between the flow equalizers, leakage through the valves, and compliance in the flow equalizer. The first problem is fairly easily detected visually and is primarily a maintenance issue. Leakage through the valve is an important design issue since it is difficult to detect and correct.

Compliance is also a design issue. It is an error that is caused by volume difference associated with pressure. At the beginning of a flow cycle of the block that is connected the dialyzer, the full side is pressurized to about 15 psig. This occurred on the previous cycle at end of stroke and was controlled by the supply regulator. The empty side is at approximately drain pressure. After flow has cycled through the dialyzer the returning fluid side goes up to about 15 psig as controlled by the input pressure equalizer. The output side after emptying goes to dialysate pressure approximately. Therefore inaccuracies occur due to differences in the supply pressure and the input pressure equalizer pressure or due to differences in pressure going out to the drain and out to the dialyzer.

The input pressure equalizer very accurately controls pressure of fluid returning from the dialyzer to the supply pressure. This is accomplished by a device that has a chamber separated by a diaphragm which has a valve mounted on one side. Flow from the supply regulator flows through one side. Fluid returning from the dialyzer flows through the other side. Recirculation flow around the dialysate pump is controlled by the valve. At end of stroke the full pump flow is recirculated and therefore pressure can very accurately be controlled.

Both pressures of fluids exiting the flow equalizer are controlled by the output pressure equalizer. It has a chamber separated by a diaphragm with valves attached on both sides. The two fluids enter on each side of the diaphragm and exit through the ports controlled by the two valves. Therefore the flow stream going to the higher pressure forces the diaphragm to the other side, restricting flow and creating a pressure drop that boost the pressure to equal the pressure on the higher side.

The flow equalizer controls overall flow through the machine. This flow could vary as much as 10% with no problems if it were not for the fact that it is part of the proportioning system. It meters dialysate flow while two concentrate pumps meter concentrate into the flow path. They work together to accurately control proportioning rati s. According to the design specification the proportioning ratio should be accurate within ±2%. This ratio accuracy is dependent on flow equalizer accuracy (F) and concentrate pump accuracy (C). For acetate proportioning there are 35 parts of dialysate per part of acetate concentrate so the ratio accuracy is

$$\frac{35(1+F)}{(1-C)} - 35 = 0.02$$

$$35$$

$$F = .02 - 1.02C$$

If concentrate pump accuracy is assumed to be ±1.4%, which is v ry generous, flow equalizer accuracy has to be ±0.57% which is also easily accomplished

In addition to accurately proportioning the fluids, they must also be well mixed to maintain a relatively constant conductivity. This objective is achieved partially by having mix chambers, but also by maintaining a fairly constant flow through the machine. It is desirable, then, to have the diaphragms reach end of stroke at very near the time for the valves to switch. This controlled no flow time must occur when flow is varied from 500 to 1000 mL/min and dialysate pressure changes from –400 to +600 mmHg. It is accomplished by a system that incorporates pressure equalizers, end of stroke sensors and speed control on the supply pump.

The pressure equalizers control both input pressures to be equal and both output pressures equal. Since both blocks are identical there is an equal pressure drop across a equal restriction and therefore equal flow.

The end f str ke sensor, which are thermistors mounted at the outlets to the flow equalizer sense the abrupt change in flow at end of

stroke. Based on a comparison of time until end of stroke with required time until valves switch th speed is controlled to the supply pump. The system attempts to control no flow time to 1 second. If time for valve switch comes before the end _f stroke has been sensed, the proportioners are stopped until an end of stroke occurs and then the valves are switched. This procedure preserves the proportioning ratio while allowing the flow to drop.

Test Data

Valve Leakage

Valve leakage was tested at both the inlet and outlet. Out of 8 valves, the minimum pressure that caused leakage was 50 psig. Outlet pressures exceeded 100 psig with no leakage.

The data demonstrates that the valves far exceed their requirements. They will be exposed to a maximum of 20 psig in the machine.

Due to their construction the type M valves function much better than diaphragm valves that have been used in this application. The diaphragm valves are very sensitive to outlet pressure which is exposed to the whole diaphragm area and provides a substantial force. Due to the bellows design outlet pressure provides no vertical force on the valve stem. The advantage of this feature was demonstrated by no leakage with outlet pressures exceeding 100 psig.

Flow Equalization Accuracy

Accuracy test were performed throughout the project. Accuracy ranged from –12 to +6.6 mL/h at 750 mL/min flow to –14.4 to +33.6 mL/h at 750 mL/min flow . On the first clinical machine the error increased to +60 mL/h.

A fairly extensive investigation revealed that this accuracy reduction has two causes. There was a compliance error due to flexing of the wall on the flow equalizer block. These blocks were somewhat thinner due to two dimensions which were slightly out of specification but had been accepted.

Also this flexing problem may have existed before but was masked due to better pressure matching by the output pressure equalizer. The output pressure equalizer was capable of maintaining equal pressures during no flow at end of stroke previously because the valve was better able to prevent pressure leaks. The valve size had to be increased, though, due to a reliability problem. This change decreased its sealing ability.

The accuracy problem was partially corrected by sandwiching the block between two 3/16 inch stainless steel plates. To prevent the block from being sucked in under a vacuum, a 1.5 inch diameter disk 0.005 inch thick of double sticky tape was applied at the center between the outer blocks and the steel plates and between the two center blocks.

Additional accuracy improvement was achieved by changing the seat on the output pressure equalizer to reduce its surface area in contact with the valve. The changes brought the acurracy back within the design specification of ±30 mL/h.

Flow Control

Two complete flow paths have been operating 24 hours per day. One has operated for about 15 months and the other for 12 months. One flow path ran on concentrates for 1 month. It was bleached regularly on a daily basis for six months. The valves have operated flawlessly.

UF Removal Flowmeter

The UF removal flowmeter consists of two identical cavities separated by a thin elastomer diaphragm. Each of the cavities is connected to the common port of a 3-way solenoid valve. When one of the valves is actuated and a fluid under pressure is applied to the normally closed port, the associated cavity fills, forcing the diaphragm against the wall of the opposite cavity and forcing any fluid in that cavity out through the normally open port of the associated valve. When the first valve is released and the other valve is actuated the diaphragm moves back, forcing fluid out of the unpressurized side of the flowmeter. Since the amount of fluid released with each movement of the diaphragm is always the same, this device can be used to very accurately meter the flow from inlet to outlet.

Areas of Development

Design of Cavities

It was necessary to determine the optimal cavity volume, which had to be small enough to provide good resolution of flow measurement and large enough to reduce the importance of valving errors. A cavity volume of 1 to 1.5 mL was found to be suitable.

Cavities with smooth surfaces were found to lead to unpredictable diaphragm movement, so various patterns of grooves were tested. A single pair of diametrical grooves proved satisfactory.

Initial testing with three connector passages joining each cavity to the valve port showed poor purging of fluid from the flowmeter, and a single passage near the top of the cavity gave best results.

A related problem was providing a sealing surface between the cavities. Since the diaphragm is a soft elastomer, it was important to avoid concentrated squeeze on it. It was found that good results could be obtained by using essentially flat sealing surfaces, with a very small (<0.01 inch) sealing ring. If assembly torque was controlled to 7 to 9 in-lb, repeatable performance was possible.

Diaphragm

The main considerations for diaphragm selection include resistance to swelling or degradation by heat-clean temperature fluids and by disinfectants. Although the chemical environment is less severe than that found in the proportioners (the disinfectants are diluted 34:1) the thinness of the diaphragm material exacerbates the effect of fluid contact. In the course of development we tested various materials including EPR, EPDM, and silicone. Most materials tested swelled so much after prolonged fluid contact that the diaphragm tended to get creases and folds, resulting in erratic stroke volumes. Eventually we f und a particular formulation of silicone rubber which showed no water absorption or swelling after several w eks of immersion in the whole range of fluid envir nments.

Other important considerations are physical properties including stiffness and tear resistance. An excessively high durometer material will not readily conform to the cavity shape, while an excessively soft material becomes severely def rmed by the pressure of the sealing surfaces, becoming extruded into the cavity and resulting in wrinkles. The Silicone material in a 0.020-inch thick sheet has proved to be the best so far.

Valves

A prime requirement for the UFR flowmeter control valve is minimum actuation time. This is because of the large pressure differential across the valve. All the valves tested are make-before-break, and there is an interval when the inlet and outlet ports are connected directly. Testing showed that there was a small net stroke volume error directly related to the pressure across the valve. In some early tests we used four 2-way valves with a small delay between the closing of one pair and the opening of the other pair. The amount of improvement did not justify the added complexity. Instead, the flow path design was changed to reduce the required pressure drop across the valves to less than 5 psi. At this value the flow through error becomes exceedingly small.

Another consideration for the valve is durability. A typical valve must be able to withstand continuous immersion in water, dialysate, or disinfectant solution, as well as periodic exposure to temperatures in the range of 90 to 95°C.

Initially a type MS valve was used, but the valve was unable to withstand the operating conditions for suitable lengths of time. Eventually the same type M 3-way valve used in the proportioners was substituted. These valves have superior flow and flow through characteristics, and are rated for 50 million cycles. They have performed faultlessly in the life testing.

Gear Pumps

Description

There are three magnetic drive gear pumps in the System 1000 hydraulic system, the deair, supply, and dialysate pumps. They have a cylindrical 316 stainless steel housing with two 1/8 inch NPT ports positioned radially at 180° to each other. The 1/2-inch long gears are molded from carbon filled polyphenylene sulfide. The central gear is connected through a shaft to a teflon coated cylindrical magnet which is surrounded by a stainless steel cup. A ring shaped magnet which is attached to the motor shaft surrounds the cup and provides a magnetic coupling. This coupling allows a completely enclosed pump with no seals.

Deair Pump/Dialysate Pump Assembly

The deair and dialysate pumps are mounted on the same 24 V dc motor, at opposite ends.

The deair pump draws the water/"A" concentrate mixture from the air gap chamber at atmospheric pressure through the sprayer where it drops to -500 mmHg at the pump inlet. The voltage to the motor is calibrated to provide this pressure while the machine is operating at 1000 mL/min flow.

deair pressure ranged from –452 to –520 mmHg due to the changing load on the dialysate pump from the extrem s; –400 mmHg dialysate pressure and 1000 mL/min flow to +400 mmHg and 500 mL/min flow. The pO_2 ranged from 111 to 128 which is within the desired range. When ±10% voltage tolerance is combined with the range of hydraulic conditions, the deair pressure goes from –385 to –615 mmHg and pO_2 from 88 to 143. Other dialysis machines sold in the US have been tested and pO_2 values of 150 and above were found.

The sprayer restriction has a major impact on deair and dialysate pump flow since the motor voltage is calibrated to provide a deair pressure of –500 mmHg. Therefore the pressure drop through the sprayer is 500 mmHg and the flow required to provide that pressure drop will vary with tolerances of the sprayer. That required flow along with the tolerances of the pump will determine the required RPM's of the motor. That RPM, along with the tolerances of the dialysate pump will determine the dialysate pump flow under the hydraulic conditions of for the calibration. Due to dialysate flow and pressure changes the output of the dialysate pump goes from 11.5 to 25 psig and the input goes from –400 to +600 mmHg. On top of all these conditions, we have a voltage tolerance ±10%.

We performed test to determine what flow variation we would see in a sample of 12 sprayers. With a 500 mmHg pressure differential the flow varied from 1788 to 1509. We determined that part of this fluctuation is due to the spray cone blocking part of the orifice when it is screwed into the block. These same sprayers were retested with a 0.020-inch thick washer, spacer installed to prevent the obstruction. The flow varied from 1654 to 1923. The flow was increased but was no more consistent.

This flow range is somewhat high and may be difficult to achieve with the motor that we are using. We decided to go to the next smaller size nozzle. The first nozzle was rated at 0.50 gal/min at 10 psig. The next smaller one is rated at 0.41 gal/min at 10 psig. Based on our current average flow of 1740 mL/min multiplied by the ratio of the rated flows we should expect an average flow of 1426 mL/min.

Pressure Regulators

There are five pressure regulators in the flow path; water pressure, supply, and UF removal regulators, and the input and output pressure equalizers.

Many of the parts are common to the various regulators. The supply regulator and input and output pressure equalizers use the following common parts; body, diaphragm, valve stem, diaphragm backing plates, and hardware. The supply regulator uses the same spring adjustment part as the type A regulator.

The water pressure regulator is brought off the shelf. The supply pressure can be set at 7 psig. The pressure requirement is merely enough to overcome the restrictions of the inlet water valve, heat exchanger, heater, and supply valve before dropping into the air gap at atmospheric pressure.

The supply regulator is a spring adjusted pressure reli f valve. When the force of fluid pressure on the diaphragm area exceeds the spring

force the supply regulator valve opens and allows recirculation back to the input of the supply pump. During a stroke of the flow equalizer, the supply regulator valve is closed and the pressure is controlled by voltage (RPM) to the supply pump. At the end of str ke, pressure in the supply regulator climbs to its adjusted set point and the valve opens to recirculate the full flow of the supply pump.

The input and output pressure equalizers work similarly and their function is described in the flow equalizer report.

The UF removal regulator provides a relatively constant pressure of 5 psig to the UF removal flow meter. There is a flow restriction down stream of the dialysate pump which must provide a pressure at the inlet to the UF removal regulator that is above its control pressure. It receives a pusitile flow controlled by the 1.5 mL strokes of the UF removal flow meter. Its input pressure varies with dialysate flow and pressure.

The regulator is borrowed from the 480 where it serves a similar function. The spring was changed to allow a slightly higher control pressure. This was necessary to assure that the higher 4 L/h UF removal rate could be achieved.

Results

The water pressure regulator is the same as the one in the 480 and is used in the same application so no specific testing was done on it. It is set at 8 psig in the clinical machine.

The supply regulator is set to 16 psig. This pressure is sufficient to provide full flow at 1000 mL/min and 400 mmHg dialysate pressure.

The latest valve stem in the supply regulator has been in the B prototype hydraulics for 4 months. It is in this regulator that the stem is forced against the seat the hardest since it must resist the full spring force when there is no pressure under the diaphragm. This force is about 25 lb. Inspection of the valve reveals a ring where it contacts the orifice but no major deformation.

An extensive test was done to observe on a chart reorder the four pressures of the two pressure equalizers under the full range of hydraulic conditions in a simulated treatment. Pressures were monitored at flows of 500, 800 and 1000 mL/min and dialysate pressures of –400 to +600 mmHg. Dialysate pressures were achieved by adjusting blood flows and UF removal rates.

The two input pressures tracked beautifully at all dialysate pressures and flows of 500 and 800 mL/min. The dialysate pump side dropped lower than the supply pump side at 1000 mL/min flow. They tracked well at +600 mmHg dialysate pressure but the differential increased from 1 to 7 psi as the dialysate pressure went from 300 to –400 mmHg. This phenomenon is due to insufficient capacity of the dialysate pump. It can be corrected by increasing the voltage to the double pump motor.

Pressures up and downstream of the UF removal regulator were tested under the same conditions as the pressure equalizer test. The minimum input pressure of 11.5 psig occurred at 500 mL/min flow and a negative dialysate pressure. The maximum pressure of 28 psig

occurred at end of stroke when flow was set at 1000 mL/min and dialysate pressure was 500 mmHg (the maximum tested). The output pressure remained within 205 to 280 mmHg. This minimum pressure is sufficient to provide a 4 L/min UF removal rate and the pressure differential is low enough to have a minimal impact on accuracy.

Proportioning Pumps

The design of the System 1000 proportioners combines a reciprocating plunger with a molded-on elastomeric diaphragm. The motion of the plunger is controlled by motor-driven cam and a return spring. Fluid motion is controlled by a three-way solenoid valve whose action is keyed to the plunger position. The use of a stepper motor to drive the cam allows precise control of both the speed of the pump and the operation of the valve. The cam shape is optimized relative to the mixing flowpath to provide a constant rate of infusion of concentrate.

Areas Of Development

Cam Profile

In the "A" concentrate pump the cam provides a uniform 0.1 inch lift over about 310 degrees of rotation. The plunger forces approximately 1 mL of concentrate out of the diaphragm cavity. At this point the 3-way valve is actuated and the cam radius decreases over about 50 degrees. A concentric coil spring returns the plunger to its original position at uniform acceleration. Fresh concentrate is drawn into the diaphragm cavity.

The "B" concentrate pump normally operates at a higher speed, and in order to ensure complete filling during the intake stroke, it was necessary to increase the intake duration to 180 degrees. These optimum cam profiles were arrived at after exhaustive testing of various configurations.

Extended performance testing of the cams involved measuring stroke volume accuracy over the specified range of flows and inlet and outlet pressures. Overall stroke volume accuracy (using 3.75-foot inlet line) was about ±0.6%.

Material Selection

For low-stress components such as the pump body and the plunger cartridge, primary importance was given to good chemical and temperature characteristics and resistance to cracking. For these components CPVC, Delrin, and Ultem were found to be satisfactory. The cam and cam follower materials are relatively heavily loaded, and materials such as brass, Noryl, glass-filled plastics, and Nytuff-coated aluminum were evaluated in the accelerated test fixture. Delrin AF was found to have superior durability. The metal parts of the pumps - plunger stems, cam-follower carriers, and fasteners - are made of 316 stainless. Both the accelerated cam/cam follower life test and the proportioner life test show that the selected materials will have adequate durability for the specified life of the machine.

Plunger Material

Owing to the extreme chemical and temperature environments within the pumping chamber, a great deal of work was required to find a

suitable elastomer for the plunger. Eventually a precisely-defined EPDM compound was specified.

This compound has been life tested for the equivalent of 9 months of worst-case clinical use without impairment of function.

Control Valves

Important considerations in selecting the valve included:

- rapid actuation and release to minimize backflow through the valve cavity

- adequate orifice size to handle the high instantaneous fluid velocities during the inlet stroke

- resistance to chemical attack and to high temperature

- durability - life expectancy in excess of 50 million cycles

Initially a type MS 3-way valve was used, but after problems with durability, it was replaced with a type M 3-way valve. Testing has shown the type M valve to have superior flow characteristics and low backflow. This valve shows chemical and temperature resistance far superior to the type MS valve.

Spring

A variety of springs were compared to arrive at the optimum combination of minumum spring force consistent with proportioning accuracy and long life. Based upon the results of these test a new spring was designed and produced. So far this spring has been tested in excess of 50 million cycles (5+ years worst-case clinical use equivalent) with no failure.

Other Considerations

- **Effect of high and low inlet and outlet pressures:** Both A and B proportioners are normally required to draw concentrate from a container only 2 to 3 feet below the pump, it was deemed prudent to determine the effect of a raised concentrate container on the pumping accuracy. Tests showed that raising the inlet pressure had a small but predictable effect on the stroke volume. Tests indicate that most of this error is due to backflow through the valve during actuation or release when there is a momentary uninterrupted path for fluid through the valve. A much lesser effect is in distortion of the diaphragm which tends to reduce stroke volume. Tests confirm that the stroke volume error is closely related to the actuation time of the valve being used. The currently used valve showed a maximum flowthrough per stroke of less than 0.01 mL at a pressure differential across the valve of 3 psi.

- **Effect of inlet line length and diameter:** There appears to be a complex interrelationship between the characteristics of the inlet line the action of the valve, and resultant stroke volume. At minimum pump rates the inlet line has no effect on stroke volume. As the rate increases, a 'supercharging' effect produces an increase in stroke volume. It appears that the rapidly moving fluid in the inlet line tends to slow the closing of the valve and to pressurize the diaphragm cavity. (In fact, the pressure pulse tends

to distort the diaphragm and increase the pump capacity momentarily. This effect is documented by a set of comparisons of inlet lengths coupled with comparison of diaphragms of different durometers.) Eventually, at still higher speed, stroke volume falls off rapidly due to incomplete filling of the pump cavity. The supercharging effect is affected by inlet tube length and valve actuation time. The maximum pump rate before stroke volume falloff is directly related to inlet tube diameter. Numerous tests were carried out to quantify the errors and to arrive at the optimal inlet tube. Eventually a silicone rubber inlet line 45 inches long by 0.125 ID was decided on. This resulted in acceptable stroke volume accuracy over the desired flow range (<0.5% at 36 rpm). The above studies were done using water as the pumped fluid. It was later discovered that the use of the denser concentrate (specific gravity = 1.16) exagerated the problems, particularly the high flow dropoff. Use of a 0.187 ID inlet tube rectified the problem. Fortunately this phenomenon appeared to be limited to pumps using the type S valves. When the type M valve was substituted the net error (supercharging vs. dropoff) at 900 mL/min flowrate was about 1% with either size tubing.

- **Effect of inlet concentrate filter:** A filter on the concentrate inlet line is to prevent particulate matter from damaging the valve seal or entering the flowpath. The two effects that such a filter can have are increased negative pressure on the valve inlet (both initially and after extended use) and effects associated with the trapping of a volume of air inside the filter. A number of filter types were tested and found not to affect proportioner performance significantly.

Test Fixtures

A number of test fixtures were developed in order to evaluate the performance and durability of various designs, components, and materials. These included the following:

1. PC-based controller circuits which allowed controlling the motor speed and valve action of the proportioners. These were used in conjunction with various mass-measurement fixtures to track pump stroke volumes and pump rates. In some tests there were additional provisions for producing variable inlet and outlet pressures.

2. A motor driven test fixture on which up to eight cams could be mounted and rotated at accurately controlled speeds. The fixture included provision for testing the springs and the cam follower assemblies. With this fixture it was possible to run accelerated tests on the above components and to arrive at opitimal configurations and materials in a relatively short period of time.

3. A life test fixture using valves, heaters, and a programmable controller. With this fixture it was possible to simulate all of the chemical and temperature environments to which the proportioners would be subjected to in clinical use. Over the past seven months this fixture has been used to determine the durability of the proportioners (particularly the plunger

diaphragms and the valves) as well as to evaluate such ancillary components as concentrate filters. While such a fixture necessarily must operate under real-time conditions, some of the components have been under test for the equivalent of 9 months clinical usage.

In addition to the above described fixtures, proportioners were mounted in a series of hydraulic prototype modules as well as in the first of the clinical prototypes. Over a period of months, upward of 6000 hours have been accumulated on the various proportioners.

Dialysate Flow Control System Performance

Description

The purpose of the dialysate flow control system is to accurately control the dialysate flow rate in the System 1000 machine and minimize the flow dead time between flow equalizer valve switches. The System 1000 machine utilizes a double acting diaphragm metering device (referred to as the flow equalizer) to match the volume of dialysate delivered to the dialyzer with the volume of dialysate pumped back from the dialyzer.

The System 1000 flow path contains three pumps, two of which are powered by the same motor which runs at a constant speed (deair and negative pressure pumps). The deair pump is situated in a flow loop with the deair sprayer (directly after the A mixpoint) to produce a low pressure that removes the dissolved air in the water being prepared as dialysate. The negative pressure pump is in the post dialyzer flow circuit and provides the pressure which draws the fluid from the dialyzer and delivers it to the flow equalizer. This pump runs at a constant speed and has a recirculation flow path around it so that the flow through the pump remains constant even though the flow equalizer flow is pulsitile. The supply pump the pump which supplies the fresh dialysate flow to the flow equalizer. This pump's speed is controlled to accomodate different dialysate flow rates.

Since the flow equalizer has a fixed volume, the time between valve switches determines the dialysate flow rate provided that the total volume of one side of the flow equalizer has been filled and the other side emptied. To ensure a complete volume transfer in the flow equalizer, flow sensors (End of Stroke Sensors) have been strategically placed in the flow path to sense when the flow stops (End of Stroke). The valves will not switch before the end of stroke condition is sensed (unless a secondary timeout condition is encountered). The speed of the supply pump determines the instantaneous flow rate of the dialysate and is controlled so as to minimize the end of stroke time (the time remaining in the flow cycle until valve switch). In this way, complete flow transfer of the flow equalizer is guaranteed every flow equalizer cycle and the dead time is minimized.

Test Data

The flow control system testing was split by function into six different parts.

Dialysate Flow Rate Accuracy

The dialysate flow rate accuracy was tested by first calibrating the flow rate using the calibration routine, then gravimetrically measuring the dialysate flow rate (drain flow rate) at different set flow rates. The testing illustrated a maximum dialysate flow rate error of less than 0.5%.

End of Stroke Reliability

The end of stroke reliability was tested by recording the number and frequency of the end of stroke errors that occur upon flow rate changes and dialysate pressure changes. The end of stroke errors consist of four different errors:

No flow alarm

This error is reported when no end of stroke signal is sensed before the secondary flow cycle timeout occurs for four consecutive flow cycles.

Early end of stroke on sensor 1

This error is reported when sensor 1 senses an end of stroke condition before half of the flow cycle time has elapsed.

Early end of stroke on sensor 2

Same as above, except for end of stroke sensor 2.

Too much time between end of stroke signals

This error is reported when there is more than 2.55 seconds between the end of stroke signals.

Dialysate flow rate changes produced one set of early end of stroke errors (sensors 1 and 2) only when stepped from low to high flow. This condition is explainable by the fact that when the flow rate is stepped up the supply pump drive voltage is instantly increased to accommodate the higher flow rate yet the flow equalizer valve period left over from the lower flow rate is still counting down thereby creating the early end of stroke condition. In summary, the end of stroke errors occur very seldom and are not considered likely enough or important enough for machine response. For trouble-shooting purposes the machine will display the errors in technician mode only.

End of Stroke Dead Time Control (distribution around desired)

End of stroke dead time control testing was done in two tests. In the first test, the end of stroke time for each sensor was logged for a period of 45 minutes as two flow rate steps at 15 minute intervals were imposed on the machine. The second test was the same as the first except two dialysate pressure steps were introduced at 15 minute intervals. The end of stroke tests showed that the worst case step response to any of the above conditions was after the high to low flow rate step which took a total of 7 flow equalizer cycles to fully return back to the previous steady state conditions (at 500 mL/min flow rate 7 flow equalizer cycles takes a total of 95 seconds).

No Fl w Alarm

The no flow alarm testing involved disabling the supply pump in the System 1000 machine after the flow rate stabilized and measuring the number of flow equalizer cycles that occur before a no flow alarm error is displayed. With the supply pump disabled the machine will not have any dialysate flow and will not sense end of stroke. If end of stroke is not sensed the machine waits only 5 seconds after the time it expects the end of stroke signal and then switches the flow equalizer valves (secondary flow equalizer timeout). The above test repeatably indicated that after four secondary flow equalizer timeouts the no flow alarm error is reported.

Closed System Integrity

Power Derating of Components

The deratings of the components involved with the flow control system were calculated under worst case conditions for each component. The components involved include:

Supply pump drive circuitry

Deair/negative pressure pumps drive circuitry

Flow equalizer drive circuitry

Rinse valve drive circuitry

End of stroke sensors and drive circuitry

Toxicity Testing

The toxicity testing consisted of three parts: a biological reactivity test, hemolysis test, and heavy metals test. These tests were performed on a sample of a 24 hour 3 liter recirculation water extract of the entire dialysate flow path. The biological testing was comparable to the Elution Method of USP XXII "Biological Reactivity Test" #87; the mammalian cell line was MRC-5, human embryonic lung tissue. Hemolysis testing was performed using rabbit blood and the amount of hemolytic activity of the extract was measured. The test for heavy metals was based upon USP XXII "Heavy Metals Test" #231. The flow path extract (undiluted) passed all three tests. It was found to be non-toxic to the cells and induced less than 5% hemolysis; the total concentration of heavy metals was less than 10 ppm.

The average of these errors is 19.1 mV, suggesting that an input ffset to the A/D converter existed. This offset w uld be compensated with the software calibration of the pressure input.

In the System 1000, the pressure is calibrated at two points, typically 0 and 300 mmHg. Calibrating the A/D values around these two pressures and then plotting the error between these calibrated pressures and the measured pressures results in the following graph:

A/D Pressure Measurement Accuracy
(A/D Measured − Actual)
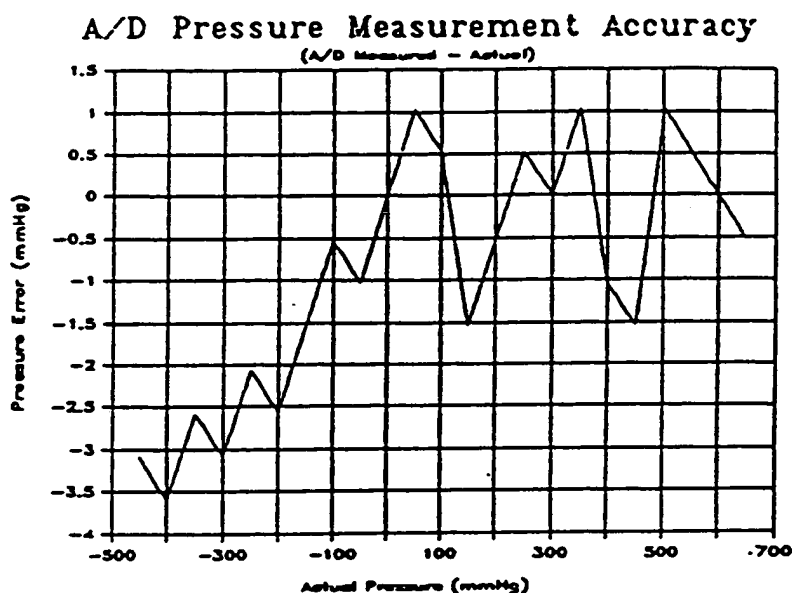
Summary

The extracorporeal blood pressure measurement system was analyzed using the venous pressure input, which is identical to the arterial and expansion chamber pressure inputs. The testing consisted of applying a pressure to the pressure transducer input, and then measuring the output of the pressure amplifier output and the output of the A/D converter. The applied pressure range was from −450 to +650 mmHg. The displayed pressure range of the venous and arterial pressur s in the machine is −400 to +600 mmHg.

An analysis of the pressure amplifier output shows a pressure tranducer linearity of within ±2.5mmHg over the applied pressure range. The same data reveals a peak error near zero pressure, indicating a slight gain difference between positive and negative pressures.

A comparison of the applied pressure with a calibrated A/D pressure output indicates a pressure accuracy of +1.0 to 1.5 mmHg over the calibrated range of 0 to +300 mmHg, and an accuracy of +1.0 t −3.5 mmHg over the entire applied pressure range. Accuracy of the negative pressure range could potentially be improved by implementing a separate calibration gain for this range. However, even with the single calibration range, the accuracy is within the desired resolution of ±5 mmHg.

Blood Pump Control System Pow r Requirements

Description

The Blood Pump Control system consists of the Blood Pump Controller board and the Blood Pump Power board. The Blood Pump Controller board utilizes +5V and ±12V, which it receives through the Mother board connector. The Blood Pump Power board also utilizes these same voltages, which it receives through harnessing from the Blood Pump Controller board. In addition the Power board utilizes +24V, which it receives through harnessing directly from the +24V power supply.

Test Data

The +5 V, +12 V, and −12 V current loads for the Blood Pump system were measured by plugging the Blood Pump Controller board into a Mother board extender card, and inserting a current meter in series with the power connection being measured. Since the +5 V supply uses two connector pins, one was left disconnected during its measurement. The state of the Blood Pump System during the measurements was with the blood pump off, the level adjust pump off, and the heparin pump motor energized but not stepping. This was not felt to have significant impact on the measurements since these functions draw power primarily from the +24 V supply. The following are the results:

Power Supply	W/ Power Brd (mA)	W/O Fower Brd (mA)	Calc Pwr Brd (mA)
+5V	316.0	251.0	65.0
+12V	120.5	24.2	96.3
-12V	16.5	16.3	0.2
+5V			
±12V			

The W/ Power Brd column was measured with the Power board plugged into the Controller board, while the W/O Power Brd column was measured with the Power board unplugged. The Calc Pwr Brd column is the difference between the previous two columns.

The +24 V supply current was measured at the point where it connects to the Blood Pump Power board. During all measurements the heparin pump was energized but not stepping. Measurements were taken with the following Blood Pump conditions:

- Blood pump off

- Blood pump running with new 0.25-inch ID tubing at 250 mL/min (Low load).

- Blood pump running new water filled occluded T8 tubing at 500 mL/min (Heavy load).

For each of the above conditions, two measurements were taken, one with the level adjust pump off and one with it on. The measurements were not stable, therefore each data point is shown as a range, with the average of the high and low values in parenthesis. The results are shown in the following table, with all values in mA:

Blood Pump	Level Adjust	Level Adjust
Load	Off	On
Off	387 - 429 (408)	542 - 629 (586)
Low Load	806 - 1043 (925)	944 - 1212 (1078)
Heavy Load	2120 - 2140 (2130)	2270 - 2290 (2280)
		+24V

By taking an average of the differences between the Level Adjust pump being on and off gives an approximate level adjust current draw of 160 mA. By averaging the differences between the Blood Pump being on and off gives approximate blood pump current draws of 504 mA for the low load and 1.71 A for the heavy load.

Summary

The power supply requirements for the Blood Pump Control system were measured, which included current measurements for the +5 V, +12 V, –12 V, and +24 V supplies. The following table summarizes the results. The low value for the +24 V current is with the Level Adjust and Blood Pump motors off. The high value is with the Level Adjust on and the Blood Pump running at 500 mL/min while loaded with water filled occluded T8 tubing.

Power Supply	Load Current (mA)
+5V	316.0
+12V	120.5
–12V	16.5
+24V	408 - 2280

UF/Proportioning System

Proportioning Control

Description

The purpose of the concentrate pump controller is to provide the proper drive signals for each concentrate pump assembly so that user specified proportioning ratios can be accurately controlled. Each concentrate pump consists of a stepper motor driven (by a cam/follower) diaphragm pump assembly that utilizes the proper actuation of a three way solenoid valve for its intake and output pumping strokes. The valve actuation (intake stroke) is synchronized by a signal that is generated by an optical interrupter sensor which senses a pin mounted on the cam of the pump assembly. When the controller receives a synchronization pulse it actuates the associated pump's valve for a given number of stepper motor steps ("A" pump 28 steps and "B" pump 100 steps). The "A" concentrate pump has a 14% intake stroke duty cycle and the "B" concentrate pump has a 50% intake stroke duty cycle, due to cam configuration. The "A" concentrate pump cam has an 86% output stroke duty cycle to minimize the "A" concentrate output flow rate dead time. Since the maximum "B" concentrate pump's flow rate is nearly twice the "A" its flow duty cycle can not be altered to give it a longer duration output stroke (the "B" concentrate is also easily deaired at low pressure).

The UF/PROP controller utilizes the fact that the number of motor steps between each synchronization pulse is 200 to check the concentrate pumps for stepping errors. If the synch pulse is received late then the motor is assumed to be skipping steps and the error is reported. If received early, the synch pulse is reported as a noise error (these error conditions are displayed in technician mode).

The four phase, 200 step/rev stepper motors used in the concentrate pumps are driven in the full step mode, which utilizes the relationship that two coil states are always in the inverse state (ON/OFF) of the other two. Therefore only two logic lines are used to step the four phases of each motor. For each motor these two logic lines are inverted and the resulting four signals are buffered by NPN transistors contained in ULN2065 ICs. These four open collector outputs are connected to the ends of the two motor coils and the coils' center taps are connected to the +24V supply. The inductive currents produced by the stepper motors' coils are conducted through the flyback diodes in the ULN2065 through a Zener diode connected to the +24V supply. The resulting collector voltage, limited by the Zener diode, is used to help quicken the deenergization of each coil. This increases the maximum speed attainable by the motors and more importantly increases their output torque capability at all speeds (coil denergizes through only 22 V, since the center taps are connected to the +24 V supply).

When the operator enters the desired dialysate flow rate the host (80XX microcontroller) converts this flow rate, the technician set proportioning ratio (unless acetate proportioning is determined from the concentrate interlock sensors), and the concentrate pump calibration constant to the concentrate pump speed. The concentrate pump speed is in the form of a time between stepper motor steps and

has units of the 7.8125 μsec per step (2/256 msec per step). The speed (period) calculated is then written to the UF/PROP controller (8040).

Test Data

Proportioning Accuracy

The proportioning accuracy testing was done in four pieces (not including the total system verification). The first test was to determine if the UF/PROP controller (8040) controls the speed of the concentrate pumps to the desired speeds it is passed. This test measured a speed error of less than 0.06% (less than the measurement error).

The second test, which was done to illustrate the correct concentrate pump valve timing, showed that within 0.5% the "A" concentrate pump has an intake stroke duty cycle of 14% and the "B" concentrate pump has an intake stroke duty cycle of 50%. The error is most likely experimental error since it is less than the error associated with a one step (which is 0.5%). In any case the error is of an acceptable level.

The third test was to verify that the controller is passed the correct concentrate pump speeds from the host. The speed the controller is passed is dependent on the dialysate flow rate, the proportioning ratio, and the concentrate pump's calibration constant. The test data collected demonstrates that the desired pump speeds sent to the controller are the correct speeds as represented by their integer values. The quantization error introduced by the integer pump speeds (and dialysate flow rates) was analyzed to show that the maximum proportioning ratio error introduced was less than 0.12%.

Extensive testing was done to show that the proportioning pumps' stroke volumes are constant over flow rate and pumping head height. The testing produced volume errors of less than 0.6% over the full range of tested parameters.

In conclusion, since the concentrate pump stroke volumes are constant over flow and head height, the actuation of the concentrate pump valves is correct, and the speed that the pumps are controlled to is correct then the concentrate pump flow rates must be accurate and stable.

The forth test used to verify the proportioning accuracy was to measure the dialysate flow rate accuracy. This test measured dialysate flow rate errors less than 0.4%.

Set Flow (mL/min)	Measured Flow (mL/min)	Error
500	501.6	0.32%
700	701.6	0.23%
900	900.83	0.09%
500	498.7	0.26%
700	700.97	0.13%
1000	1000.1	0.01%

The final proportioning accuracy test was to measure the System 1000 conductivity over many minutes and analyze the conductivity stability with a desired dialysate flow rate change. A graph of one sample run is presented below. The test conditions include acetate proportioning, dialysate flow rate of 500 mL/min from start to a time of 76 minutes, and dialysate flow rate of 800 mL/min from time of 76 minutes to test end.

Conductivity

mS/cm

14.4
14.2
14
13.8
13.6
13.4
13.2
13
12.8
12.6
12.4
12.2
12

Dialysate Flow
Rate Changed
to 800 mL/min

0 9 18 26 35 44 52 61 70 78 87 96

Time in Minutes
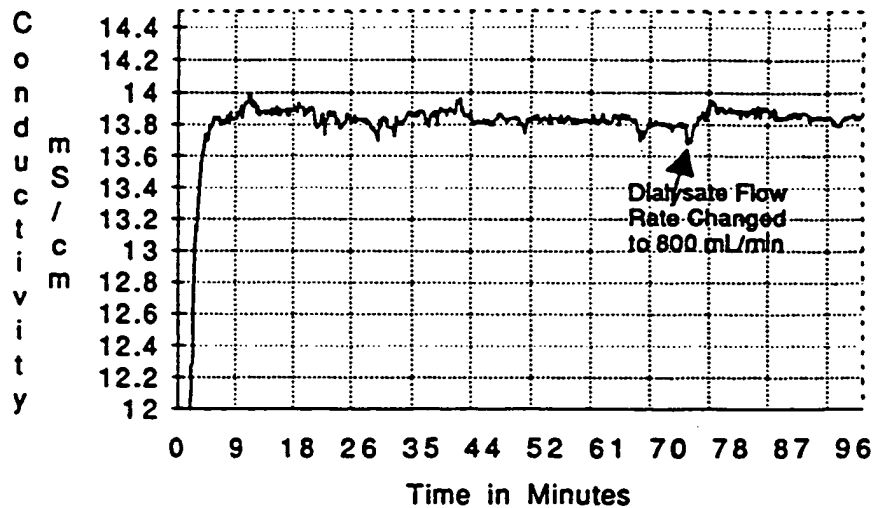
Similar testing to that above was done with a bicarb proportioning. Test results indicate that the short term final conductivity stability at 500 mL/min dialysate flow rate is ±0.1 mS/cm and at 1000 mL/min is ±0.05 mS/cm. The "A" and "B" probe conductivities indicate worst case short term conductivity stabilities of ±0.3 and 0.5 mS/cm at dialysate flow rates of 500 mL/min.

Proportioning Stability

The short term stability of the concentrate pumps' speeds can vary from step to step by as much as 50%, yet on a revolution to revolution basis the speed stability variability is limited to only 0.2% (2 msec per revolution at maximum speed of 60 RPM, minimum controller value of 641). These values represent the nature of the drive and are not thought of as deficiencies in the drive scheme.

The proportioning stability was measured a variety of ways. The first was to measure the period of each step of a repeating step waveform. This test showed that the expected step waveform was output, and was repeated over time.

The second test was to measure the number of steps over a multiple minute period knowing the desired step rate. This test is the same test as was used to verify the speed accuracy of the concentrate pumps. It shows the pump speeds to be stable and accurate to within 0.05% of the desired speed.

One of the final tests used to measure proportioning stability was to log the System 1000 machine conductivity over a many minute period. The test which generated the graph below was performed on the monitoring machine #1 with acetate proportioning at a dialysate flow rate of 500 mL/min. This graph shows that no m asurable conductivity drift was noticed in a two hour period. The test also indicates that the short term conductivity stability at the final probe

is n the order of ±0.05 mS/cm. The test also measur d the "A" and "B" conductivity probe stabilities to be ±0.4 and 0.1 mS/cm, respectively.

SATRN Conductivity over Time During Acetate Proportioning
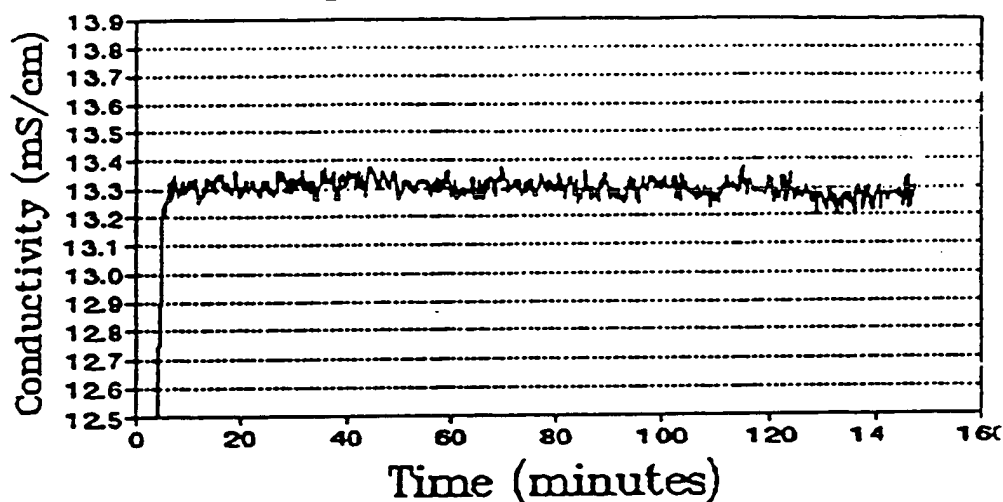
Subsequent testing of the machine was done which simulated a patient treatment using bicarb proportioning at a dialysate flow rate of 600 mL/min. Machine parameters were recorded throughout the treatment and the conductivity of the machine was found to be stable to within 0.1 mS (displayed conductivity was 13.3 mS ± 0.1 mS) ver a 4 hour period.

The conductivity stability data over any other data illustrates the proportioning stability of the System 1000 machine.

Power Derating of Components

The power derating of the concentrate pump driver circuitry located on the UF/PROP POWER board (revision Z7) was measured/ calculated under the worst case conditions for the associated parts (maximum speed for the Zener diode and flyback resistor, and 0 RPM for the transistor driver package).

Many different drive schemes were tested to determine which could provide enough torque without producing an excessive amount of audible noise. The full step drive mode with the elevated voltage flyback current path was found to offer the best compromise of the two requirements. Dynometer testing was done to determine how much torque the motors are capable of delivering throughout the required speed range. The torque sp ed curve f the data c llected is sh wn below.

Torque versus Speed for
Stepper Motor PH268-23. Full Step Drive

Torque versus Speed graph: X-axis "Speed (RPM)" from 0 to 60, Y-axis "Torque (oz in)" from 0 to 130. Curve starts at ~125 oz-in and decreases to ~55 oz-in at 60 RPM.
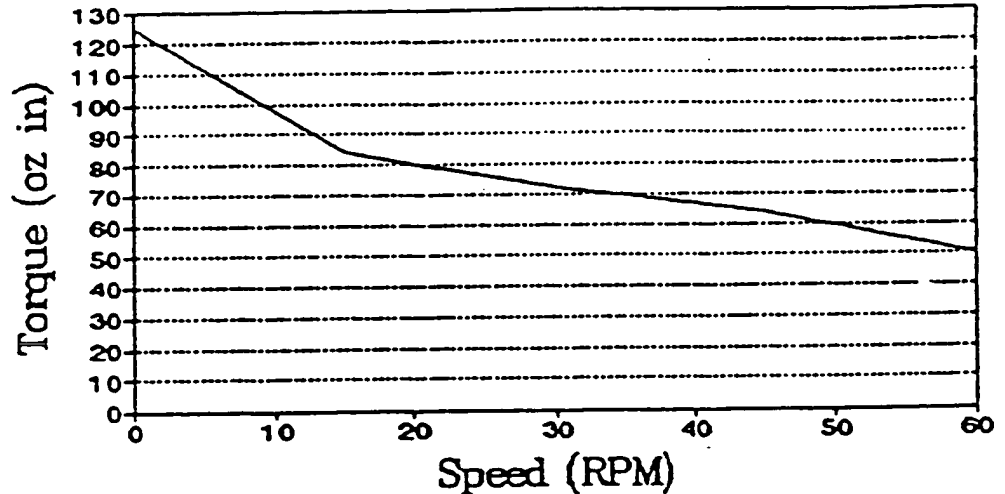
Transistor Driver Package ULN2065

The maximum temperature rise measured for this part under all the different test conditions was less than 26°C. The maximum power measured was less than 0.4 W. Since the thermal impedance of the part (junction to case) is 10 to 13°C/W (supplied by the manufacturer) the maximum junction to ambient rise can be determined to be less than 32°C. Typically these parts have a maximum junction temperature of 150°C (maximum junction temperature not specified by the manufacturer), therefore at the System 1000 design maximum internal ambient temperature of 60°C the maximum allowed temperature rise from junction to ambient is 90°C. Since the maximum measured rise was less than 32°C the part derating can be calculated to be greater than 64%.

A second way of verifying the part derating is to compare the maximum measured power of 0.4 W with the manufacturer's maximum power rating at the System 1000 maximum internal ambient specification of 60°C. The manufacturer specified that at 60°C the maximum package power dissipation should not exceed 2 W. This method indicates that the derating of the driver is 80%.

Zener Diode 1N4748

The Zener diode derating was calculated as 1 minus the measured power divided by the maximum allowed power at the maximum lead temperature (measured lead temperature rise plus the maximum ambient temperature). The maximum measured temperature rise was less than 20°C and the maximum pow r measured was 0.19 W. Th manufacturer specifies the maximum power dissipation at a lead temperature of 85°C of 0.75 W. Therefore, the worst case derating of the Zener diodes is 1 − 0.19/0.75 = 74%.

Flyback Resistor 1k 2W

The maximum power in the resistor is only a function of the voltage that is placed across it. Since the voltage across this r sistor is the Zener voltage (and not 100% duty cycle) the maximum power in the resistor is 24*24/1000 or 0.576 W. Therefore the derating is 1 – 0.576/2 or 71%. This component never is operated at 100% duty cycle, so the actual derating is greater than 71%.

Summary

The System 1000 machine specification for proportioning accuracy is ±2%. The proportioning accuracy demonstrated by the System 1000 machine was shown to be better than 1%. The 1% value was the result of both the accuracy and stability measured during testing.

Dialysate Flow Control

Description

The purpose of the dialysate flow control system is to accurately control the dialysate flow rate in the System 1000 machine and minimize the flow dead time between flow equalizer valve switches. The System 1000 machine utilizes a double acting diaphragm metering device (referred to as the flow equalizer) to match the volume of dialysate delivered to the dialyzer with the volume of dialysate pumped back from the dialyzer.

The System 1000 flow path contains three pumps, two of which are powered by the same motor that runs at a constant speed (deair and dialysate pressure pumps). The deair pump is situated in a flow loop with the deair sprayer (directly after the "A" mixpoint) to produce a low pressure that removes the dissolved air in the water being prepared as dialysate. The dialysate pressure pump is in the post dialyzer flow circuit and provides the pressure which draws the fluid from the dialyzer and delivers it to the flow equalizer. This pump runs at a constant speed and has a recirculation flow path around it so that the flow through the pump remains constant even though the flow equalizer flow is pulsitile. The supply pump supplies the fresh dialysate flow to the flow equalizer. This pump's speed is controlled to accommodate different dialysate flow rates.

Since the flow equalizer has a fixed volume, the time between valve switches determines the dialysate flow rate, provided that the total volume of both sides of the flow equalizer have filled and/or emptied. To ensure a complete volume transfer in the flow equalizer, flow sensors (End of Stroke Sensors) have been strategically placed in the flow path to sense when the flow stops (End of Stroke). The valves will not switch before the end of stroke condition is sensed (unless a secondary timeout condition is encountered). Since the speed of the supply pump determines the instantaneous dialysate flow rate, it is controlled so that both end of stroke signals are received in a predefined amount of time before the desired valve switch time (this time is adjustable and is set to 1 second upon initialization). In this way, complete flow transfer of the flow equalizer is guaranteed every flow equalizer cycle and the dead tim is controlled.

T st Data

The flow control system testing was split by function into five different parts.

Dialysate Fl w Rate Accuracy

The dialysate flow rate accuracy was tested by first calibrating the flow rate using the calibration routine, then gravimetrically measuring the dialysate flow rate (drain flow rate) at different set flow rates. The testing illustrated a maximum dialysate flow rate error of less than 0.5%.

End of Stroke Reliability

The end of stroke reliability was tested by recording the number and frequency of the end of stroke errors that occur upon flow rate changes and dialysate pressure changes. Other testing counted the number of errors that occur over a multiple hour treatment when the machine is operated with typical treatment conditions. There are four different end of stroke errors:

No flow alarm

This error is reported when no end of stroke signal is sensed bef re the secondary flow cycle timeout occurs for four consecutive flow cycles.

Early end of stroke on sensor 1

This error is reported when sensor 1 senses an end of stroke condition before half of the flow cycle time has elapsed.

Early end of stroke on sensor 2

Same as above, except for end of stroke sensor 2.

Too much time between end of stroke signals

This error is reported when there is more than 2.55 seconds between the end of stroke signals.

Dialysate flow rate changes produced one set of early end of stroke errors (sensors 1 and 2) only when stepped from low to high flow. This condition is explainable by the fact that when the flow rate is stepped up the supply pump drive voltage is instantly increased to accommodate the higher flow rate yet the flow equalizer valve period left over from the lower flow rate is still counting down thereby creating the early end of stroke condition.

In summary, the end of stroke errors occur very seldom and are not considered likely enough or important enough for machine response. For troubleshooting purposes the machine will display the errors in technician mode only.

End of Stroke Dead Time Control (distribution around desired)

End of stroke dead time control testing was done in two tests. In the first test, the end of stroke time for each sensor was logged for a period of 45 minutes as two flow rate steps at 15 minute intervals were imposed on the machine. The second test was the same as the first except two dialysate pressure steps were introduced at 15 minute

.

intervals. The end of stroke tests showed that the worst case step response to any of the above conditions was after the high to low flow rate step which took a total of 7 flow equalizer cycles to fully return back to the previous steady state conditi ns (at 500 mL/min flow rate 7 flow equalizer cycles takes a total of 95 seconds).

No Flow Alarm

The no flow alarm testing involved disabling the supply pump in the System 1000 machine after the flow rate has stabilized and measuring the number of flow equalizer cycles that occur before a no flow alarm error is displayed. With the supply pump disabled the machine will not have any dialysate flow and will not sense end of stroke. If end of stroke is not sensed the machine waits only 5 seconds after the time it expects the end of stroke signal and then switches the flow equalizer valves (secondary flow equalizer timeout). The above test repeatably indicated that after four secondary flow equalizer timeouts the no flow alarm error is reported.

Power Derating of Components

The deratings of the components involved with the flow control system were calculated under worst case conditions for each component at an internal ambient temperature of 60°C. The components involved include: the shutdown transistor, the supply pump drive circuitry, the deair/dialysate pressure pump circuitry, the flow equalizer valve drive circuitry, the rinse valve drive circuitry, and the end of stroke sensors/drivers.

Shutdown Transistor

The shutdown transistor is used as a redundant switch to the critical power loads (switched +24V supply) driven by the UF/PROP power board. The loads include: the supply pump, the deair pump, the two concentrate pumps, and the UF removal meter valves. Under worst case conditions (supply and deair motors stalled) the maximum current load on the transistor averages about 2.1 A. With an average current level of 2.1 A the power dissipated in shutdown transistor, Q11, was calculated to be 2.1 W. This power level corresponds to a derating of slightly greater than 50%. The derating is marginal yet the stalled motors condition in the System 1000 machine is a state which can last only a couple of minutes before the operator will have to turn the machine off to be repaired.

Supply pump drive circuitry

The supply pump drive circuitry utilizes a Pulse Width Modulated drive from the switched +24 V supply with a frequency of about 22 kHz and a peak current limit of about 2.5 A. When the supply pump drive circuit was tested the supply pump motor being used in the System 1000 machine was the type F motor. This is the reason why the current limit circuitry was set to operate at the extreme current of 2.5 A. When tested with the type F motor the drive transistor, Q10 was found to be derated by greater than 70% and the flyback diode, D22, 75%. Since the type F motor has been replaced with an type A ironless r tor motor (like the one used for the deair/dialysate pressure pumps) the circuit has been changed to be the same as was tested for the deair/dialysate pressure pump motor. This drive transistor, Q13,

was determined to be derated by 68% and its flyback diode, D23, was found to be derated by 88%. Q10 and D22 will then be derated the same as the Q13 and D23 since the derating is independent of operating load (derating determined at stall).

Deair/dialysate pressure pumps drive circuitry

The deair/dialysate pressure pumps drive circuitry utilizes a Pulse Width Modulated drive from the switched +24V supply with a frequency of about 22 kHz and a peak current limit of about 1.6 A. When the current limit testing was done on the deair/dialysate pressure drive circuitry the motor used was type A. The derating of the deair/dialysate pressure pump drive transistor, Q13, was calculated under stall condition to be 68%. The derating of the deair/dialysate pressure pump flyback diode, D23, was calculated to be 88% during the same test.

Flow equalizer drive circuitry

The flow equalizer valve drivers, Q4 and Q5 (MTP3055E), conduct the current which power the flow equalizer valves. The current typically averages about 1.5 A at 50% duty cycle with a period range of 6.7 to 13.5 seconds. The power dissipated in the devices was calculated to be 0.11 W (at 100% duty cycle) and their derating was found to be greater than 86%.

There exists flyback diodes, D16 and D17 (MR501), on the UF/PROP power board which conduct current each time the associated flow equalizer valve set is deenergized. When tested no appreciable temperature rise was measured for the devices and the "on" duty cycle was measured to be less than 0.6%. Therefore derating of these devices is reasoned to be proper.

Rinse valve drive circuitry

The rinse valve driver, Q8 (MTP3055E), conducts the current which powers the rinse valve (SIRAI D301 with EF4 Soleniod). The current is less than 0.2 A. The derating for this device was not directly calculated since the current level is so low and no measurable temperature rise was found. The derating can be reasoned to be greater than 90% since the same device (MTP3055E) is used to switch currents levels that are 8 times greater than the rinse valve current and that device (flow equalizer valve driver) was found to be derated by over 86%.

End of stroke sensors and drive circuitry

The end of stroke sensors drivers are DC current sources, U9 and U10 (LM317), which energize the end of stroke sensors with 18.3 mA of current derived from the +24 V supply. When energized and placed in heated water the typical end of stroke sensor voltage drop is about 13 V. In air the sensor voltage is about 6 V. Since a current source is used to self heat the thermistors as the sensor temperature increases, the sensor resistance decreases, the power into the device drops. In this way the power delivered to the sensor is limited to insure proper sensor derating. When the sensor is in air, worst case, the power dissipated by the current source was measured to be 0.43 W with a temperature rise of 41.5°C. The part power derating was then calculated to be 52%. The derating was also calculated under worst

case wet conditions and was found to be 69%. Since the dry sensor conditions won't typically exist in the System 1000 machine the 52% derating is presented for reference only.

Under worst case conditions, in air, the voltage across the end of stroke thermistors can be as low as 5.9 V (sensor resistance of 322 ohms) which from the resistance to temperature relationship of the Victory T35A11 thermistor suggests a thermistor temperature of about 110°C. The thermistors have a maximum continuous operation temperature of 325°C.

Using a dialysate temperature of 37°C and figuring the derating of the thermistors on temperature rise percentage basis, the derating of the thermistors is greater than 70%.

Summary

The dialysate flow rate accuracy demonstrated by the System 1000 machine of better than 0.5% easily meets the System 1000 machine specification of ±3%.

Testing illustrated the reliability of the end of stroke sensors and verified the proper indication of the associated end of stroke errors. The end of stroke dead time control testing proved that compensation to the most severe flow rate disturbances occurs in less than 8 flow equalizer cycles.

Finally, all the power components used in the flow equalizer control circuitry were found to be adequately derated.

UF Removal

Description

The purpose of the UF removal system is to accurately meter th volume of fluid removed from the dialysate and control the rate at which it is removed. The operator enters the volume of ultrafiltrate to remove and the UF removal rate. The host then converts these values using the appropriate calibration constant (the volume of the UF removal metering device) to the number of UF metering device strokes and the period between strokes. The UF/PROP controller is sent these values and, when the machine state is favorable, is commanded (through the use of an enable register) to commence UF removal.

The volume of the UF metering device is calibrated by having the operator measure the output weight of a multiple number of device strokes. Upon the entry of the total weight by the operator, the calibration routine calculates the average stroke weight (volume) and saves the calibration constant in the form of a percentage variance from the nominal. The UF removal metering device calibration constant has a range of ±12% and a resolution of 0.1 percent (calculated using a nominal volume of 1.5 mL).

Test Data

UF/PROP Controller Verification

The first test consisted of passing the UF/PROP controller a UF rate and then measuring the actual rate and analyzing the output waveform. The UF rate was measured by accumulating the output

volume of the UF removal metering device and counting the number of strokes stroked by the device in a 30 minute period. The volume measurement produced less than 0.5% error and the stroke count measurement produced less than 0.05% error. This test could have introduced the v lumetric error by incorrectly determining the UF removal meter's volume per stroke. This test was using the hydraulic test fixture for the purpose of verifying the correct timing of the UF removal meter valves. It can be concluded that the timing error associated with the UF removal meter is negligible and the stroke volume calibration is the critical link in the UF removal system.

The UF removal meter drive waveform was also analyzed to verify that the expected waveform was output for a given rate. Since the output waveform period is a multiple of 0.4 second periods (as designed) to achieve rates which are not even multiples of the 0.4 second period, the stroke period must alternate between the two 0.4 second multiple periods in which the desired period falls between. In this test, a desired stroke period of 1.4 seconds (3.5 * 0.4 seconds) was entered and the output waveform was recorded. The output period alternated between 1.2 and 1.6 second stroke periods as expected.

Calibration Verification

The second test of the UF removal system was to verify that the calibration of the UF removal meter volume correctly corrected the UF removal rate passed to the UF/PROP controller. This test verifi d that the correct rate is passed to the controller as determined by the UF removal meter's calibration constant. The associated error produced by the quantitization of the UF removal rate was also shown to be less than 0.05%.

Total System Accuracy

The final test of the UF removal system was done on a calibrated System 1000 machine. This test was done by entering a desired UF volume to be removed and a rate at which it was to be removed (in the dialyze mode). A volume of 1.00 L and a rate of 4.00 L/h were used for the test and the variables measured were the time for the volume to be removed, the volume output of the UF removal device and the actual volume removed across a dialyzer from a simulated patient.

The test results showed that the UF removal rate and accumulated volume accuracy, measured at the output of the UF removal device, to be better than 30 mL/h. The accuracy measured across the dialyzer was within 50 mL/h (the weight difference is believed to be caused by changes in the venous and arterial drip chamber levels).

Power Derating of Components

The power in the UF removal meter's valve drivers (MTP3055E) was measured to be 0.011 W. Since the allowable power dissipation in an MTP3055E is over 1 W the UF removal meter valve driver's deratings are greater than 90%.

Summary

The System 1000 machine specification states that the UF removal system will remove volume from the dialysate with an associated err r f less than 2%. The machine UF removal error was demonstrated to be less than 1%.

A design goal for all System 1000 electrical components was, under worst case conditions, to achieve a derating of greater than 50% with an internal ambient temperature of 60°C. The UF removal system power components meet this design goal with greater than 90% deratings.

The data presented verifies that the UF removal system performs within the specifications of the System 1000 machine.

Conductivity Measurement

Description

The purpose of the conductivity measurement system is to accurately measure and report the temperature compensated dialysate conductivity from multiple locations within the fluid path. There are three conductivity probes in the System 1000 flow path. The first probe is situated directly after the air trap which is down stream of the "A" mixpoint and is referred to a the "A" conductivity probe. The second probe is right after the "B" mixchamber and is referred to as the "B" conductivity probe. The third, referred to as the primary probe, is immediately before the bypass valve. The "A" and "B" conductivity probes are used for backup alarms and for proportioning verification. The primary probe's conductivity is used for primary alarms and is the displayed conductivity. The "A" and "B" conductivities are measured and calculated by the UF/PROP microcontroller (8040) and are passed to the host on a routine basis. The primary conductivity is measured and calculated by the MISC/IO microcontroller and is passed to the host on a regular basis for the conductivity display. The conductivity probes are calibrated in the System 1000 machine's calibration mode by having the "A" concentrate pump run at a proportioning ratio of 40:1. When the primary conductivity is determined to be stable the three conductivities are set equal to an independent reference conductivity through the use of the three programmable gain constants contained within the two controllers.

The conductivity probes are essentially tubes of fluid, 0.375 inches in diameter and 1.2 inches in length, which separate two electrodes. One of the electrodes within each probe contains a thermistor so that the temperature within each probe can be measured.

The conductivity is measured by the controllers using circuitry which does an AC resistance measurement between each of the conductivity probe's electrodes. An AC resistance measurement is used since a DC resistance measurement would polarize the electrodes and produce incorrect measurements. One electrode f each conductivity probe is stimulated with a 1 kHz AC voltage while the other is held at virtual ground (current sense electrode). Two DC voltages are produced by the circuit, one of which is proportional to the negative peak of the AC stimulation voltage (VREF) and the other which is proportional to the negative peak of the AC probe current (VCONDO) as described below.

$$VREF(V) = Vprobe(V) / 3$$

$$VCONDO(V) = Iprobe(A) * 249\Omega$$

Therefore the resistance of the probe can be calculated/measured by using the relationship below.

PROBE RESISTANCE(j) = 747Ω * VREF(V) / VCONDO(V)

The System 1000 conductivity probe resistance was modeled as a function of temperature and conductivity. The resulting relationship is entered below (C is conductivity in mS/cm at 25°C and T is temperature in °C).

PROBE RESISTANCE = 600Ω * 14 mS/cm / C * (38°C + 23°C) / (T + 23°C)

Therefore by substitution and algebra it can be shown that:

C = 600Ω * 14 mS/cm * 61°C / 747Ω * VCONDO / VREF / (T + 23°C)

The UF/PROP and MISC/IO controllers use the above equation to calculate conductivity. The conductivity is calibrated by the microcontrollers by scaling the constant in the above equation. In this way, the calibration can compensate for circuit and conductivity probe tolerances.

Test Data

The conductivity testing was done in many pieces at many different stages in the conductivity circuitry development. The key factors involved in verifying the conductivity measurement system include the modeling of the conductivity probes, the accuracy testing of the resistance measurement circuitry, the determination of the temperature compensation efficacy, and the accuracy testing of the conductivity measurement system.

The conductivity probe model defined therelationship between the probe resistance and conductivity and temperature. The probe resistance equation was previously presented.

A test was done to determine the accuracy of the resistance measurement used in the conductivity circuit. This test showed that, inside the resistance range of 400 to 4000 ohms, the circuit measured resistance with an associated error of less than ±0.25% (less than the tolerance on the test resistors of 1%). This resistance range corresponds to a conductivity range of 2.1 to 21 mS/cm (System 1000 conductivity range is 7 to 17 mS/cm) and an error in terms of conductivity of lessthan ±0.05 mS/cm (maximum at 20 mS/cm).

The temperature compensation of conductivity is an integral part of any conductivity measurement. The measurement is typically compensated to indicate conductivity at 25°C. This is the standard by which most (if not all) conductivity meters are based on, including the System 1000 conductivity measurement system.

Data was taken to verify the temperature compensation of the System 1000 conductivity measurement system. The test logged the system conductivities and temperatures to a data file (every 10 seconds) while the machine was proportioning at a constant ratio and the set temperature was being stepped between three temperatures at fifteen minute intervals. The testing indicated that the maximum deviation in conductivity due to a temperature step from 35 to 39°C was 0.13 mS/cm. This temperature range is the entire System 1000 operational temperature range. This is inside the System 1000 conductivity accuracy specification of ±0.2 mS/cm.

The final test done to verify the conductivity measurement was to vary the proportioning ratio, then at each ratio measure the conductivity with an external calibrated conductivity meter and compare it with the three System 1000 machine conductivities. The test showed that the four measured conductivities agreed to within 0.06 throughout the conductivity range of 11.11 to 15.81 mS/cm.

Summary

The testing done on the conductivity measurement system verifies that the machine accurately reports the dialysate conductivity with an error of less than ±0.10 mS/cm. This error is less than the System 1000 machine specification of ±0.20 mS/cm.

Temperature Measurement

Description

The purpose of the temperature measurement system is to accurately measure and report the dialysate fluid temperature from multiple locations in the System 1000 fluid path. The primary conductivity probe temperature is used for the temperature display, the primary temperature alarm source, and temperature compensation for the primary conductivity measurement. The "A" and "B" conductivity probe temperatures are used for conductivity temperature compensation and backup alarm generation.

The temperature measurement circuit used throughout the System 1000 machine consists of a voltage divider with a Thevenin Equivalent circuit of 3062 Ω in series with a 7.55 V supply. The voltage divider circuit when connected to a Dale thermistor referenced to ground with a resistance to temperature relationship of

$$R(T) = 5000\Omega * 2.831 * exp(-0.04162 * T)\ \Omega$$

produces a voltage to temperature relationship of

$$T = (3.77\ V - Vtemp) * 12.73\ (°C/V) + 37°C.$$

The above relationship is the result of linearizing nonlinear functi ns at a 37°C midpoint. The temperature linearization above approximates the temperature to within ±0.1°C inside the temperature range of 30 to 44°C.

The tolerances on the above component parameters can be as much as 10%, therefore the temperature versus voltage relationship for each probe must be calibrated. Calibration of the temperature measurements is a two point calibration done at 30 and 40°C which results in a slope and an offset for each temperature probe. The temperature calibration is done at a high dialysate flow rate to minimize the temperature differential between the temperature probes. After the calibration data is collected, "A", "B", primary ("dialysate"), and the reference temperatures, at the desired set temperatures of 30 and 40°C. The calibration routine scales the System 1000 measured temperatures to be equal to the temperatures measured by an external temperature reference meter (placed in the dialysate line). The gains and offsets are stored in the nonvolatile RAM for later retrieval and use during the System 1000 machine initialization. The calibration gain has a ±12% adjustment range around the nominal and the calibration offset has a ±5°C adjustment range.

T st Data

The temperature accuracy tests were d ne by comparing the measured temperature at the primary conductivity probe with an external reference at several different desired temperatures and flow rates. Since the three temperature probes (contained in the "A", "B", and primary ("dialysate") conductivity probes) use the same thermistors and support circuitry, only one probe was formally tested as described above. Other data, presented in the System 1000 Temperature Control Test Report, indicates that the three measured temperatures are in agreement with each other except for offset differences due to location differences in the fluid path. The data presented below indicates a maximum temperature measurement error of 0.06°C.

Set Temp	Flow	Ref Temp	Final Temp	Error
38	500	37.68	37.70	0.02
42	800	41.24	41.21	−0.03
42	500	41.39	41.36	−0.03
34	800	33.90	33.96	0.06
34	500	33.96	34.02	0.06
38	800	37.37	37.38	0.01

Summary

The System 1000 machine specification states that the System 1000 temperature measurement system should measure temperature to within 0.3°C. The test data presented demonstrates that the System 1000 temperature measurement system is accurate to within 0.1°C.

Temperature Control

Description

The purpose of the temperature control system is to control the dialysate temperature to the temperature selected by the operator. The operator enters the desired dialysate temperature through the touch screen interface, the host converts this value using the appropriate calibration constant to a calibrated ADC value. The valu is then written to the UF/PROP controller for uses as the initial temperature control threshold.

In the System 1000 machine there exists four separate temperature measurement probes. Three of the probes are contained in the three conductivity probes (A, B, and dialysate) and the forth is located immediately after the heater. The A and B conductivity probes are located just down stream of the A and B mixpoints, respectively. The A mixpoint is upstream of the B mixpoint and both mixpoints are downstream of the heater. The dialysate conductivity probe is located just before the bypass valve and serves as an independent monitor of the temperature and conductivity. The displayed temperature and conductivity are measured at the dialysate conductivity probe.

To improve the temperature step response to a dialysate flow rate change, when the UF/PROP controller is told to change the flow rate it steps the heater duty cycle by the ratio of the old and new flow rates. In this way, the heater duty cycle is immediately corrected.

Since the temperature control thermistor is located at the output of the heater housing, the temperature it uses for control purposes has a

large amount of steady state instability (due to the flow rate fluctuations by the heater). Therefore the temperature control algorithm has a large time constant associated with its heater duty cycle correction. This is not a problem for flow step response times since a correction for flow rate changes is made immediately as was previously described.

Since the dialysate temperature at the dialyzer is dependent not only on the temperature controlled at the output of the heater housing but also the flow rate, the concentrate treatment type, the ambient temperature, and the concentrate temperature there exists a temperature compensation routine in the host. This routine determines that the temperature is stable when three successive readings, taken one minute apart, of the "B" probe temperature are within 0.05°C of each other. After the stability criteria is met, it corrects the temperature used for the control threshold by the difference in the temperature measured at the "B" probe and the user entered desired temperature. This temperature compensation is limited to a maximum of 2.8°C and can occur a maximum of every 20 minutes.

Test Data

Temperature control data was taken both on monitoring machine #1 and the stand alone flow path test station (an XT computer running a BASIC host/slave interface program linked to a UF/PROP controller, running its System 1000 control program, and a UF/PROP power board). Most of the step response tests were done on the stand alone flow path test station. These tests did not include the temperature correction logic contained within the System 1000 temperature control system. The temperature correction software was not thought to be needed for the temperature step response tests since the testing was mainly aimed at the UF/PROP control software.

The temperature control performance testing was divided into the following parts:

- Dialysate Temperature Control Accuracy
- Dialysate Temperature Control Stability
- Dialysate Temperature Step Response to:
  - Flow Changes
  - Desired Temperature Changes
  - Incoming Water Temperature Changes

Dialysate Temperature Control Accuracy

Temperature control accuracy was indirectly tested throughout the tests presented below. The test which best illustrates the temperature control accuracy is the temperature response to desired temperature changes test. This test demonstrated that the temperature control system is capable of controlling the dialysate temperature throughout the temperature range of 35 to 39°C to within 0.1°C.

Independent testing of the monitoring machine #1 was done which simulated a patient treatment using bicarb proportioning at a dialysate flow rate of 600 mL/min. The machine parameters were

periodically recorded throughout the tr atment. The data gathered indicates that the displayed temperature was within 0.2°C (after warm up) of the set temperature throughout the 4 hour treatment. The 0.2°C temperature difference was constant throughout the treatment and indicates a calibration offset.
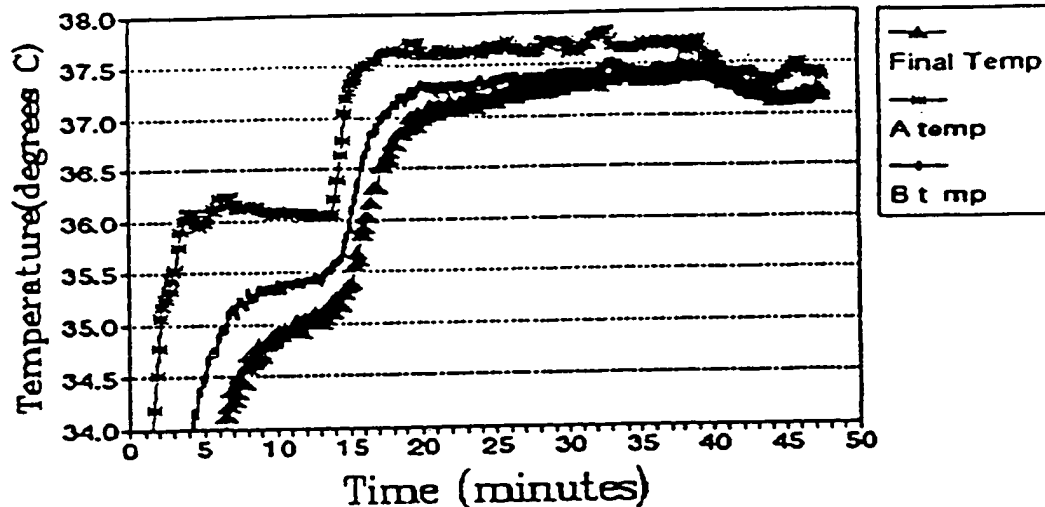
Dialysate Temperature Control Stability

Temperature stability testing consisted of many different tests. The first testing was done on the flow path test station. It collected data over an eight hour period and measured an average final temperature probe temperature of 37.45 and the maximum variation from the average of 0.16°C. This variation seems high yet the standard deviation of the data was only 0.04°C. Using the standard deviation to describe the data, 95% of the time the final temperature probe temperature can be described as 37.45 ±0.08°C.

Further testing of the dialysate temperature stability consisted of multiple data log runs on the monitoring machine #1 during a variety of treatment conditions. These data files each typically contain about 2 to 3 hours worth of data. Graphs of the data have been prepared for the documentation of the testing and a typical graph has been entered below.

The first graph shows the dialysate temperature rise of the monitoring machine #1 at 500 mL/min dialysate flow rate from a cold start. Near 15 minutes into the test, the "B" conductivity probe temperature stabilizes at about 35.5°C. At this point the "B" temperature stability test passes (since its temperature is stable to within 0.05°C for three minutes) and the set temperature is corrected in order to bring the final and the "B" conductivity probe temperatures closer to the desired temperature of 37.2°C. It can be seen that the final and "B" conductivity probe temperatures are still increasing before and after the temperature correction is made (the temperature increase is very gradual and is within the stability test criterion). This is due to the fact that the internal ambient temperature is increasing (tubing and flow path component temperatures are increasing) and the final conductivity probe temperature is dependent on the flow path compartment internal ambient. After the correction the final temperature initially stabilizes to 37.2°C, at time t=27 minutes, and slowly increases to 37.5°C in next 14 minutes. At time t=41 minutes, the temperature correction software again corrects the set temperature (since the stability test passed and the 20 minute time between corrections elapsed). After the second correction the final and B conductivity probe temperatures stabilizes to 37.2°C (the set temperature).

SATRN Temperatures versus Time From Cold Start

In conclusion, the time it takes for the machine dialysate temperature to completely stabilize is highly dependent on the flow path ambient temperature (machine ambient). The test presented below was performed with an ambient temperature of 18°C to show the effects of ambient temperature on dialysate warm up time.
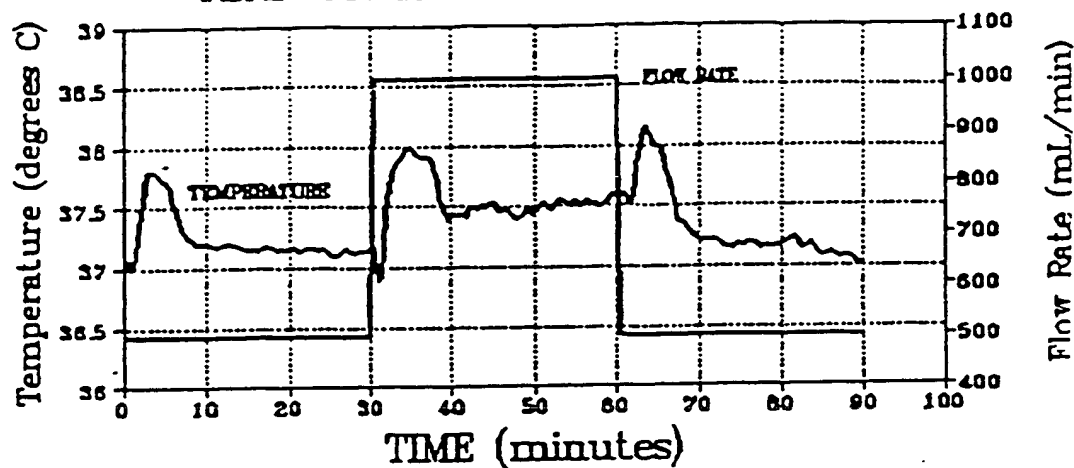
Dialysate Temperature Step Response to Flow Changes

The temperature response to flow step testing was done on the stand alone flow path test fixture. The graph below shows the temperature response at the final conductivity probe to the largest flow steps possible in the System 1000 machine (1000 mL/min and 500 mL/min). When the flow rate is increased from 500 mL/min to 1000 mL/min there is an initial temperature decrease of 0.2°C that lasts less than 2 minutes. Then the temperature increases 1.1°C (or 0.8°C from the starting temperature). After 8 minutes the temperature decreases 0.5°C and stabilizes at a temperature 0.3°C above the starting temperature.

When the flow rate is decreased from 1000 mL/min to 500 mL/min the temperature increases 0.7°C. After 7 minutes the temperature decreased 1.0°C (or 0.3°C below the temperature at the 1000 mL/min flow rate) and decreases another 0.2°C in the last 20 minutes of the test due to flow path cooling at the lower flow rate.

The temperature difference due to flow rate differences is explainable by the fact that the fluid exposure time to the flow path (heat sink) is proportionly lower at the high flow as compared to the low. This DC offset is compensated in the System 1000 machine by the temperature correction logic using the "B" temperature. The data indicates no overshoot and n instability in the heater duty cycle in response to flow rate changes.

SATRN UF SUBSYSTEM
TEMP CONTROL TESTS, LOAD REGULATION

Dialysate Temperature Step Response to Desired Temperature Changes

The first temperature response to desired temperature steps testing was done on the stand alone flow path test fixture. The graph below shows the temperature response at the final conductivity probe to desired temperature steps of about 6°C (greater than the entire temperature adjustment range in the System 1000 machine). The temperature transitions occur without any overshoot and the temperatures are stable in less than 9 minutes.

SATRN UF SUBSYSTEM
LOW TO HIGH TEMP @ 800 FLOW
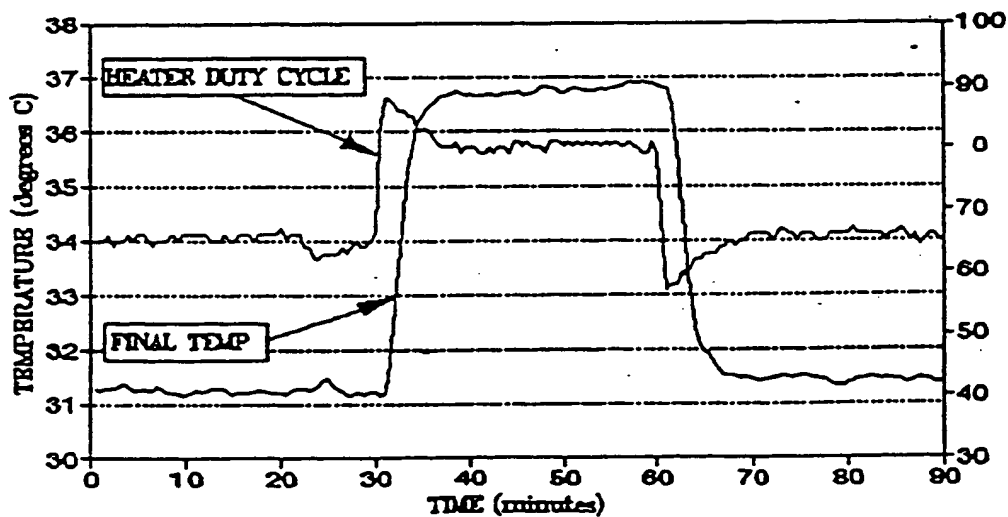
Other temperature testing of desired temperature step res...onses were done on the monitoring machine #1. The testing illustrates the efficacy of the temperature correction logic. The graph below shows the "B" c nductivity probe temperature with an initial desired temperature setting of 37°C. After some time the temperature setting was changed to 35°C, and later yet the temperature was changed to 39°C. Upon close inspection, the B temperature can be seen to first stabilize at about 36.2°C at time equal to about 10 min. The temperature is then corrected and allowed to stabilize once again at nearly 37°C. After the temperature is stepped down, at time 37 minutes, the temperature falls down to about 35.3°C and then is corrected, after which it falls to 35°C. The same two steps can be seen when the temperature is stepped to 39°C. Without these fine adjustments, the final temperature probe may read temperatures of greater than 2°C different than the entered desired temperature.

SATRN UF SUBSYSTEM
CORRECTED TEMPERATURE CONTROL
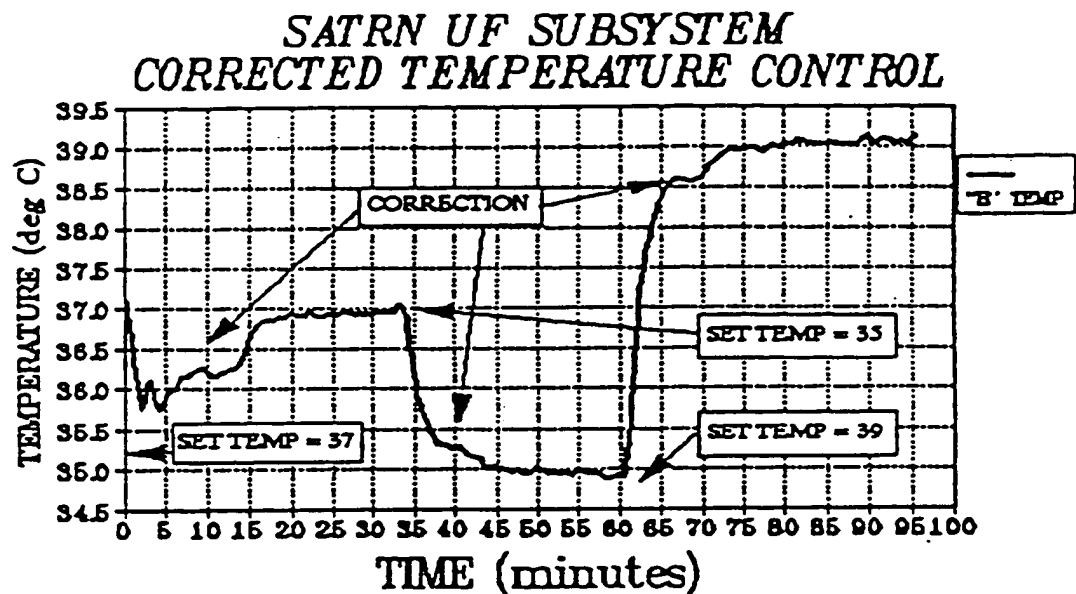
Dialysate Temperature Step Response to Incoming Water Temperature Changes

Temperature testing was done to measure the machine response to incoming water temperature steps. The final conductivity probe temperature, heater duty cycle, and the incoming water temperature were logged to a data file while the incoming water temperature was stepped from typical temperatures to temperatures less than the machine specification. The test was done at 500 and 1000 mL/min flow rates and the incoming water temperature steps were from 10°C to typically less than 5°C.

The testing revealed that the temperature instabilities at the final conductivity probe were much greater at the higher flow rates as compared to those at the lower flow rates. At 1000 mL/min dialysate flow rate the temperature spikes at the final conductivity probe in response to incoming water temperature steps of 5°C were about 1°C and required 5 minutes to be fully compensated. With the same test at 500 mL/min dialysate flow rate the temperature spikes were l ss than 0.2°C. Both tests verified that the heater duty cycle response to the incoming temperature steps was well behaved. The heater duty cycle responded with little to no overshoot, exhibited a stablesteady state (heater duty cycle fluctuations of less than ±2%), and responded quickly from step to steady state (less than 2 minutes).

Power Derating of Components

The only power device associated with the temperature control system is the solid state relay. The solid state (SS) relay derating was calculated by using the component ratings for the heat sink, the isolation pad and the solid state relay. The ratings are a SS relay junction to case thermal impedance of 0.63°C/W, a SS relay maximum junction temperature of 100°C, a SS relay power approximation of 0.9 W/A, an isolation pad thermal impedance of 0.3°C/W, and a heatsink thermal impedance of 1.4°C/W. Since the System 1000 design maximum internal ambient temperature is 60°C the SS relay maximum junction to ambient temperature rise for a 50% derating is (100 - 60)/2 = 20°C. Then the maximum power dissipation for th relay is P = 20°C / (0.63+0.3 +1.4) = 8.58 W and the maximum current capacity for a 50% derating is I = 8.58W /(0.9W/A) = 9.5 A. Since the System 1000 heater is rated at 1500 W, when powered with 120 Vac its current draw is 12.5 A. Therefore to maintain 50% derating for the SS relay the fan must run.

At the System 1000 specification for the maximum internal ambient temperature of 50°C (60 is used as design spec) the maximum SS relay current is 11.9 A. The 50°C temperature brings the maximum SS relay current closer that drawn by the heater, yet to maintain the 50% derating the fan is still required.

Summary

The testing demonstrated that the temperature stabilizes in less than 20 minutes and that this time varies with the ambient temperature and the incoming water temperture. When the desired temperature was changed, the resulting temperature transitions occured without overshooting and the temperatures stabilized in less than 9 minutes. When the dialysate flow rate was changed, the temperature stabilized within 9 minutes.

Power Supply Measurement

Description

The purpose of the power supply measurement system is to allow continuous monitoring of the +5 volt, the +12 volt, and the –12 volt power supplies.

This is accomplished by use of two resistor dividers connected to analog inputs on the UF controller board. The first divider consists of

a 10.0K 1% resistor (R13) connected to +5 volts and a 15.0K 1% resistor (R14) connect d to analog ground. This pr vides a nominal voltage of 3.00 Vdc (if +5V = 5.00 Vdc) with a 0.8% tolerance. The second divider consists of a 15.0K 1% resistor (R15) connected to +12 volts and a 24.3K 1% resistor (R16) connected to –12 volts. This provides a nominal voltage of 2.840 Vdc (if +12V = 12.00 Vdc and –12V = 12.00 Vdc) with a 4% tolerance.

The voltages from these dividers are fed into two analog inputs on the UF controller board, where they are converted to digital values by a 10 bit A/D converter. The 10 bit value from the conversion is left justified to provide a 16 bit signed value with a resolution of 4.88 mVdc. This value is averaged in the UF controller software before being passed to the host system. (NOTE: The most significant bit is always set to 0.) These values may be multiplied by [5 volts/(215-25)]) to obtain voltage values.

Test Data

To support the power supply measurement process, the analog to digital conversion process was tested and shown to be accurate to within 1.1 bit (1024), or 5.3 mV over a range of 0 to 4.95 volts. An accuracy better that 2 mV (0.4 bit) was seen from 2 to 4.95 volts. This gives a 0.1% accuracy at voltages greater than 2 volts. A graph is included showing this accuracy.

SATRN UF SUBSYSTEM
A/D CONVERSION ACCURACY
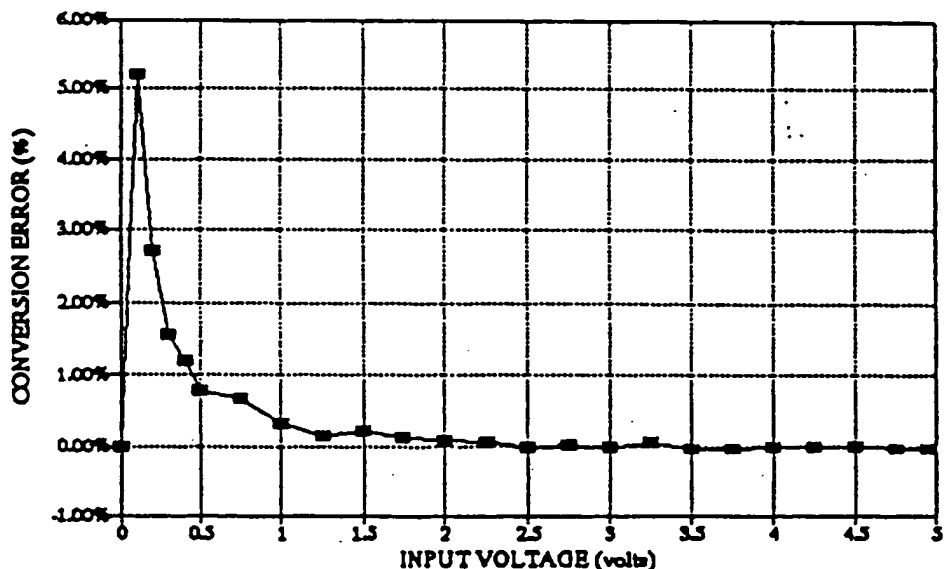
The divider voltages were measured with a digital voltmeter and compared to the digital values converted by the UF/PROP micro controller system (displayed as a tech message on the screen).

The first test measured the voltage at the junction of R13 and R14 (voltage divided from the +5 V supply) and the digital value converted by the UF/PROP micro controller (ADC channel 15, RAM locati n 100). The value stored in RAM was read several times, and the range of the values recorded.

DMM = 2.95 ADC = 19364 to 19370

The actual value of the +5 V supply (at junction of R13 and the +5 V supply) was measured as 4.92 V. The desired value at the junction of R14 & R13 would be 4.92/(15K+10K)*15K = 2.952

The ADC value was converted to a voltage by multiplying by the conversion factor (5 volts/(2^{15}-25) = 0.000152757), giving 2.9576 to 2.9585 volts which is nearly equal to the value measured by the DMM. The actual error was calculated and shown below.

(2.9576+2.9585)/2=2.95805, and [(2.95805/2.952)−1]*100=0.20%

The second test measured the voltage at the junction of R15 and R16 (the combination of the +12 V and the −12 V supplies) and the digital value converted by the UF/PROP micro controller (ADC channel 14, RAM location 98). Again, the value stored in RAM was read several times, and the range of the values recorded.

DMM = 2.97 ADC = 19476 to 19491

The actual values of the +12V (at R15) and the −12V (at R16) supplies were measured and recorded as follows:

+12V = 12.20 V −12V = −11.96V

The desired value at the junction of R15 and R16 would be

[12.2 − (−11.96)]/(15K+24.3K)*24.3K + (−11.96) = 2.9786

The ADC value was converted to a voltage by multiplying by the conversion factor [5 volts/(2^{15}-25) = 0.000152757], giving 2.9747 to 2.9770 volts which is nearly equal to the value measured by the DMM. The actual error was calculated and shown below.

(2.9747+2.9770)/2=2.9759, and [(2.9759/2.9786)−1]*100=0.09%

This gives an actual measurement error of 0.097%, well within the expected error range.

Summary

Measurement of the actual value of the +5 volt power supply voltage on the UF controller board can be accomplished with an accuracy of 1% (0.8% for the divider and 0.2% for the A/D conversion).

Measurement of the voltage resulting from the division of the +12V and −12V supplies on the UF controller board can be accomplished with an accuracy of 4.1% (4% for the divider and 0.1% for the A/D conversion).

This function will support verification of the digital and analog operational voltages in the electronic subsystems in the System 1000.

Miscellaneous Input/Output System

Blood Leak D tector

Circuit

The blood leak detection system consists of a green LED driven by a voltage-controlled current source, which in turn receives its input voltage from a digital-to-analog converter on the MISC I/O controller. The LED illuminates a photo detector on the other side of the blood leak detector housing. The photo detector is pulled up by a 750 KΩ resistor to +5 V. The voltage across the photo detector is fed to a A-to-D channel on the controller. Blood leaking from the blood tubing into the dialysate tubing results in higher photo detector resistance or higher voltage across it. Knowing the voltage theshold for a specific blood concentration allows for accurate detection of the blood leakage.

Test Set-Up

Using the harness for the monitoring machine #2, a blood leak detector circuit consisting of a green LED HLMP-3950 and a photocell CLAIREX CL-909L mounted in Polysulfone lenses were used to duplicate the actual blood leak detector components.

Different hemoglobin concentrations were used: 0, 35, 60, and 84 mg/liter. The sample solution was bathed in a temperature controlled water container at 38°C. A 7401 blood pump set at 200 mL/min circulated the liquid into the detection cell and back to the temperature-controlled bath.

An operational amplifier LM358 is used to force a programmable current in the green LED. The photocell is pulled up with a 750 KΩ resistor to a regulated supply voltage set at 9.8 volts. The cell voltage is then buffered by an LM358 before being measured by a data acquisition system using a COMPAQ computer.

Preliminary measurement showed that a black plastic bag around the test set-up was sufficient to eliminate the effect of ambient light and to simulate the internal cabinet.

Test Data

The test data show the photocell voltage as a function of the current in the green LED and the concentration of hemoglobin in the tap water. From the photocell voltage we can deduct its resistance by the formula:

$V = 9.8 \cdot R/(R+750)$ or $R = 750 \cdot V/(9.8 - V)$

The law of transmission (Lambert law) states:

$\log(Iref/I) = aLc$ or $\log(Iref) - \log(I) = aLc$

where a is the absorbancy index of hemoglobin, L the length of the medium in the direction of transmission, and c the concentration f hemoglobin, Iref is the illumination at zero concentration, and I the illumination at the concentration c, both measured at the end of the medium.

One of the purposes of the test is to establish a method to determine the concentration of leaked blood in the dialysate by optical means. The curve of photocell resistance versus illumination of the CL-909L cell provides a good approximation of that relation:

$$\log(I) = -1.011 \cdot \log(R) + 2.334543$$

(I being illumation in foot candles)

Cell Resistance Curves

Variation with Illumination CL-900 Series
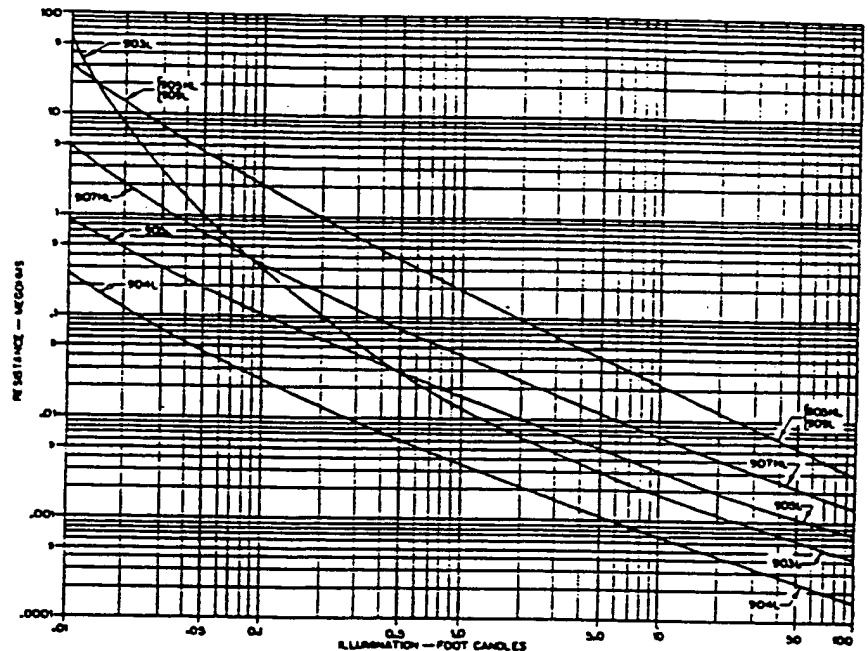
Details of the regression:

Illum	Resistance (Kohm)	log(I)	log(R)
0.1	2000	−1	3.30103
1	200	0	2.30103
7	30	0.8451	1.477121

Regression Output:

Constant	2.334543
Std Err of Y Est	0.009471
R Squared	0.999947
No. of Observations	3
Degrees of Freedom	1
X Coefficient(s)	−1.011
Std Err of Coef.	0.0073

By subtracting log(I) from log(Iref), we thus obtain the term aLc for each concentration of hemoglobin. By dividing aLc by the concentration c we obtain the constant aL which is determined by the set-up and the characteristics of hemoglobin. We can see in the column A/concen that this factor is really constant for each test (within experimentation errors) and reasonably constant between tests given the fact we are dealing with a difference of two sets of numbers of similar magnitude because of the logarithmic operations.

DATA of log(Ir f) = f(LED current) with tap water at 38°C.

04-25-1990 15:20:00   Hemoglobin concentration: 0 mg/L

LED Current	Cell Voltage	Cell Resist (K ohms)	log(I)ref
2.00	5.307	885.75	-0.646
2.50	4.595	662.03	-0.518
3.00	4.028	523.46	-0.415
3.50	3.588	433.17	-0.332
4.00	*3.221*	*367.14*	*-0.259*
4.50	2.927	319.36	-0.198
5.00	2.680	282.33	-0.144
5.50	2.471	252.82	-0.095
6.00	2.294	229.21	-0.052
6.50	2.137	209.18	-0.012
7.00	2.004	192.78	0.024
7.50	1.889	179.05	0.056
8.00	1.783	166.77	0.088
8.50	1.692	156.50	0.115
9.00	1.606	146.99	0.143
9.50	1.534	139.15	0.167
10.00	1.468	132.12	0.190
10.50	1.406	125.60	0.212
11.00	1.348	119.58	0.234
11.50	1.296	114.34	0.253
12.00	1.251	109.75	0.271
12.50	1.206	105.20	0.290
13.00	1.164	101.05	0.308
13.50	1.127	97.45	0.323
14.00	1.090	93.89	0.340
14.50	1.059	90.87	0.354
15.00	1.027	87.83	0.369
15.50	0.998	85.00	0.384
16.00	0.972	82.55	0.396
16.50	0.946	80.16	0.409
17.00	0.923	77.97	0.421
17.50	0.900	75.83	0.434
18.00	0.879	73.89	0.445
18.50	0.861	72.22	0.455
19.00	0.838	70.16	0.468
19.50	0.819	68.38	0.479
20.00	0.802	66.83	0.489
20.00	0.804	67.05	0.488
19.50	0.821	68.56	0.478
19.00	0.841	70.43	0.466

DATA with 35mg/L hemoglobin at 38°C.

04-26-1990 09:42:41

LED Current	Cell Voltage	Cell Resist (K ohms)	log(I)	log(Iref)- log(I) (or "A")	"A"/concen (c in g/L)
2.00	6.035	1202.02	-0.780	0.134	3.83
2.50	5.355	903.72	-0.655	0.137	3.90
3.00	4.789	716.65	-0.553	0.138	3.94
3.50	4.321	591.44	-0.468	0.137	3.91
4.00	*3.924*	*500.81*	*-0.395*	*0.136*	*3.90*
4.50	3.604	436.16	-0.335	0.137	3.91
5.00	3.328	385.68	-0.281	0.137	3.91

5.50	3.089	345.20	-0.232	0.137	3.91
6.00	2.882	312.50	-0.188	0.136	3.89
6.50	2.705	285.95	-0.149	0.137	3.92
7.00	2.543	262.81	-0.112	0.136	3.89
7.50	2.405	243.89	-0.079	0.136	3.88
8.00	2.283	227.75	-0.049	0.137	3.91
8.50	2.175	213.91	-0.022	0.137	3.92
9.00	2.072	201.12	0.005	0.138	3.93
9.50	1.977	189.48	0.031	0.136	3.87
10.00	1.897	180.02	0.054	0.136	3.88
10.50	1.823	171.37	0.076	0.136	3.90
11.00	1.752	163.32	0.097	0.137	3.91
11.50	1.687	155.90	0.117	0.136	3.89
12.00	1.628	149.46	0.136	0.136	3.88
12.50	1.575	143.64	0.153	0.137	3.91
13.00	1.523	138.00	0.171	0.137	3.91
13.50	1.478	133.15	0.186	0.137	3.92
14.00	1.431	128.26	0.203	0.137	3.91
14.50	1.392	124.18	0.217	0.137	3.92
15.00	1.353	120.08	0.232	0.137	3.92
15.50	1.316	116.33	0.246	0.138	3.94
16.00	1.284	113.05	0.258	0.138	3.95
16.50	1.251	109.75	0.271	0.138	3.94
17.00	1.219	106.52	0.284	0.137	3.91
17.50	1.189	103.56	0.297	0.137	3.91
18.00	1.159	100.57	0.310	0.135	3.87
18.50	1.135	98.26	0.320	0.135	3.86
19.00	1.110	95.83	0.331	0.137	3.91
19.50	1.087	93.61	0.341	0.138	3.94
20.00	1.066	91.58	0.351	0.138	3.95
20.00	1.067	91.63	0.351	0.137	3.92
19.50	1.091	93.98	0.339	0.139	3.96
19.00	1.116	96.36	0.328	0.138	3.93

DATA with 60 mg/L hemoglobin at 38 C.

04-26-1990 09:53:09

LED Current	Cell Voltage	Cell Resist (K ohms)	log(I)	log(Iref)- log(I) (or "A")	"A"/concen (c in g/L)
2.00	6.854	1744.50	-0.943	0.298	4.96
2.50	6.220	1303.20	-0.815	0.297	4.96
3.00	5.661	1025.64	-0.710	0.295	4.92
3.50	5.193	845.52	-0.625	0.294	4.90
4.00	*4.787*	*716.22*	*-0.553*	*0.293*	*4.89*
4.50	4.438	620.63	-0.490	0.292	4.86
5.00	4.143	549.18	-0.436	0.292	4.87
5.50	3.873	490.00	-0.386	0.291	4.84
6.00	3.639	443.02	-0.342	0.289	4.82
6.50	3.432	404.23	-0.301	0.289	4.82
7.00	3.251	372.30	-0.265	0.289	4.82
7.50	3.087	344.88	-0.232	0.288	4.80
8.00	2.941	321.65	-0.201	0.288	4.81
8.50	2.810	301.51	-0.173	0.288	4.80
9.00	2.683	282.75	-0.144	0.287	4.79
9.50	2.578	267.74	-0.120	0.287	4.79
10.00	2.476	253.49	-0.096	0.286	4.77
10.50	2.384	241.07	-0.074	0.286	4.77
11.00	2.296	229.53	-0.053	0.286	4.77
11.50	2.217	219.25	-0.033	0.286	4.77

12.00	2.139	209.36	-0.012	0.284	4.73
12.50	2.078	201.78	0.004	0.286	4.77
13.00	2.013	193.90	0.021	0.286	4.77
13.50	1.952	186.50	0.038	0.285	4.75
14.00	1.898	180.14	0.054	0.286	4.77
14.50	1.844	173.80	0.069	0.285	4.75
15.00	1.792	167.78	0.085	0.284	4.74
15.50	1.747	162.66	0.098	0.285	4.75
16.00	1.704	157.87	0.112	0.285	4.75
16.50	1.664	153.40	0.124	0.285	4.75
17.00	1.625	149.03	0.137	0.285	4.74
17.50	1.591	145.39	0.148	0.286	4.76
18.00	1.553	141.20	0.161	0.284	4.74
18.50	1.518	137.47	0.172	0.283	4.71
19.00	1.489	134.40	0.182	0.285	4.76
19.50	1.457	130.98	0.194	0.285	4.76
20.00	1.428	127.90	0.204	0.285	4.75
20.00	1.427	127.85	0.204	0.283	4.72
19.50	1.460	131.29	0.193	0.285	4.76
19.00	1.493	134.76	0.181	0.285	4.75

DATA with 84 mg/L hemoglobin at 38°C:

04-26-1990 10:31:18

LED Current	Cell Voltage	Cell Resist (K ohms)	log(I)	log(Iref)- log(I) (or "A")	"A"/concen (c in g/L)
2.00	7.52	2474.40	-1.097	0.451	5.37
2.50	6.96	1841.56	-0.967	0.449	5.35
3.00	6.45	1447.04	-0.861	0.447	5.32
3.50	6.01	1189.44	-0.775	0.444	5.28
4.00	*5.61*	*1002.89*	*-0.700*	*0.441*	*5.25*
4.50	5.26	869.56	-0.638	0.440	5.24
5.00	4.96	767.66	-0.583	0.439	5.23
5.50	4.68	686.69	-0.534	0.439	5.22
6.00	4.43	618.88	-0.488	0.436	5.19
6.50	4.21	564.15	-0.448	0.436	5.19
7.00	4.01	520.24	-0.412	0.436	5.19
7.50	3.84	482.28	-0.379	0.435	5.18
8.00	3.67	448.53	-0.347	0.434	5.17
8.50	3.51	418.84	-0.317	0.432	5.15
9.00	3.38	393.97	-0.290	0.433	5.15
9.50	3.25	372.14	-0.265	0.432	5.14
10.00	3.13	352.66	-0.241	0.431	5.13
10.50	3.02	334.86	-0.219	0.431	5.13
11.00	2.92	318.53	-0.197	0.430	5.12
11.50	2.83	304.24	-0.177	0.430	5.12
12.00	2.75	291.98	-0.158	0.430	5.12
12.50	2.66	279.43	-0.139	0.429	5.11
13.00	2.58	268.22	-0.121	0.429	5.10
13.50	2.51	257.66	-0.104	0.427	5.08
14.00	2.44	249.23	-0.089	0.429	5.10
14.50	2.38	239.96	-0.072	0.426	5.08
15.00	2.32	232.92	-0.059	0.428	5.10
15.50	2.26	225.15	-0.044	0.428	5.09
16.00	2.21	218.37	-0.031	0.427	5.09
16.50	2.16	212.00	-0.018	0.427	5.08
17.00	2.11	205.83	-0.005	0.426	5.08
17.50	2.06	199.92	0.008	0.426	5.07
18.00	2.02	194.61	0.020	0.425	5.06

18.50	1.98	190.07	0.030	0.425	5.06
19.00	1.94	184.64	0.043	0.425	5.06
19.50	1.90	180.54	0.053	0.426	5.08
20.00	1.87	176.65	0.062	0.427	5.08
20.00	1.87	177.10	0.061	0.427	5.08
19.50	1.90	180.48	0.053	0.425	5.06
19.00	1.94	185.40	0.041	0.425	5.06

Blood Leak detector tests

log (Voltage vs log (LED Current)
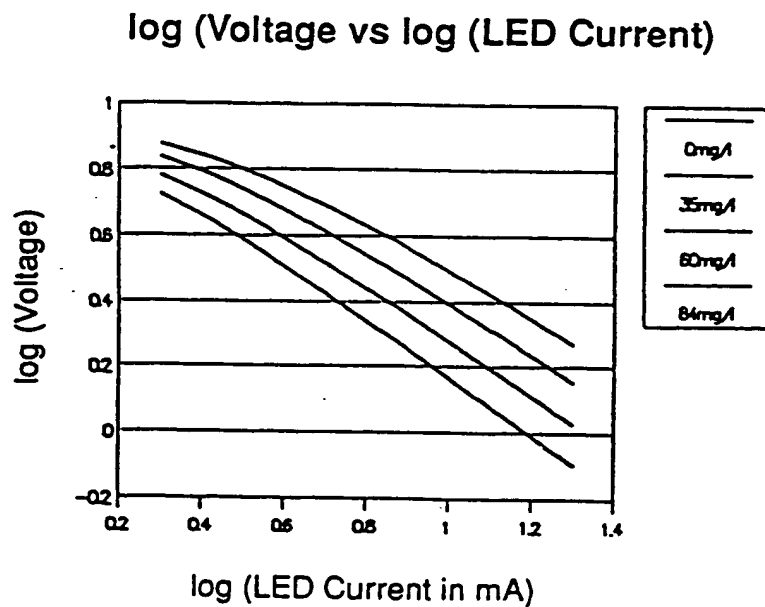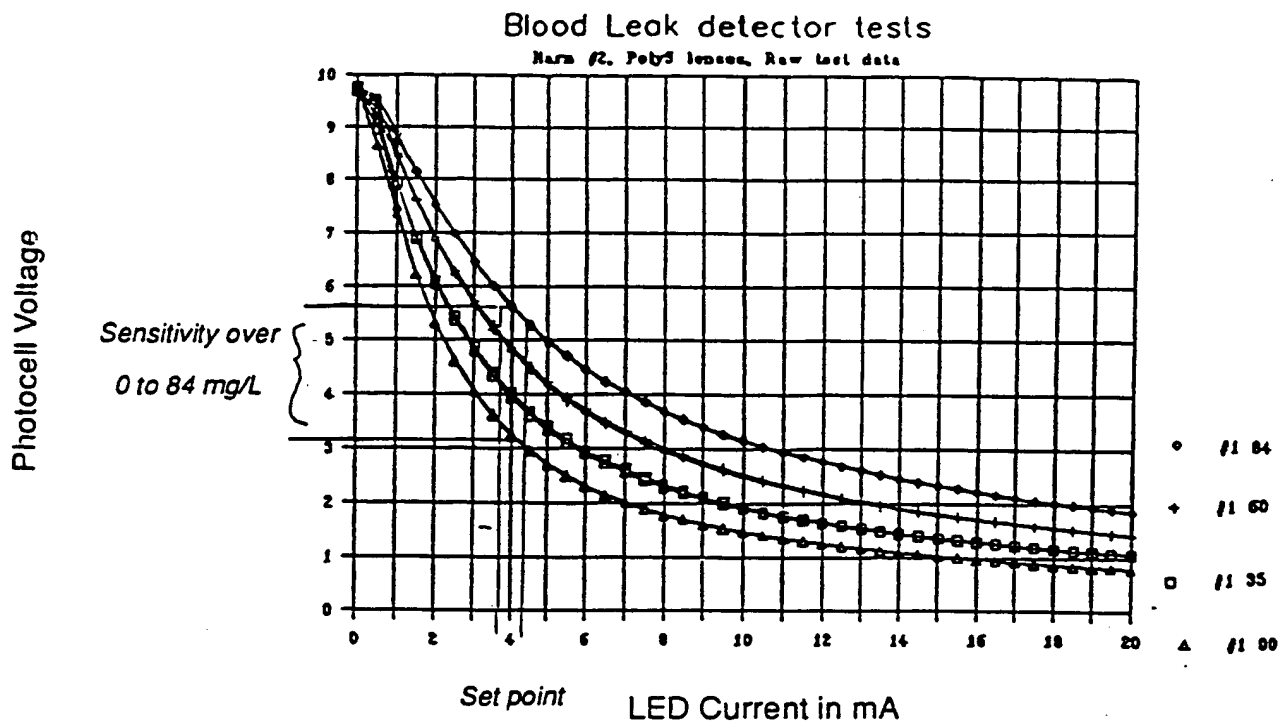
Applicati n in Blo d Leak Detection

The graph of the photocell voltag versus the LED current for different concentrations of hemoglobin is a go d indication of the photocell/LED system overall sensitivity for detection of blood. By keeping the LED current at a constant value such as 4 mA the sensitivity is more than adequate for detecting 35 milligrams of hemoglobin per liter. This is represented by a 703 mV change is photocell voltage. A system can be constructed where the LED current and/or the photocell alarm threshold voltage may be varied to compensate for changes in the photocell versus LED current family of curves. The curves will change based on manufacturing variances in the photocells, LEDs and blood leak detector assembly.

Flow Sensing

General

Flow detection is accomplished by comparing the voltage across a self heating thermistor submerged in the flow path with its voltage at no flow, which is lower as a result of its higher body temperature due to reduced cooling by the surrounding liquid. Since, the no-flow thermistor voltage is also a function of the fluid temperature, we therefore need to know the fluid temperature through the use f a non-self-heating reference thermistor submerged in the same fluid. Unfortunately, thermistor unit-to-unit variation and its own geometry and mounting make it virtually impossible to sense the dialysate flow without calibration, which is done by adjusting the IO Controller variables BPS_A and BPS_B in the formula for VFLWSENSE,no-flow:

VFLWSENSE, no-flow = BPS_A * VFLWREF/64 + BPS_B

if VFLWSENSE > VFLWSENSE, no-flow then FLOW = 1 else FLOW = 0

VFLWSENSE and VFLWREF are the values provided by the A-to-D converter, and the scaling factor 64 is used by the I/O controller to obtain the best computational accuracy with its 3-byte accumulator used in all math routines.

As one can foresee, the flow detection relies on a threshold that is a function of fluid temperature and thermistor resistance. The initial specification calls out a threshold of 5 mL/min. Such a flow rate will then result in flow indication statistically 50% of the time.

A suggested procedure to calibrate the flow detector is as follows:

- Set the dialysate temperature to a low temperature, e.g. 20°C, wait for stabilization, then note VFLWSENSE20,no-flow , VFLWREF20, VFLWSENSE20, 5 mL. The latter corresponds to 5 mL/min flow.

- Set the dialysate temperature to a high temperature, e.g. 40°C, wait for stabilization, then note VFLWSENSE40, no-flow , VFLWREF40, VFLWSENSE40, 5 mL.

- Derive BPS_A and BPS_B from the system of linear equations:

VFLWSENSE20, 5 mL = BPS_A * VFLWREF20 / 64 + BPS_B

VFLWSENSE40, 5 mL = BPS_A * VFLWREF40 / 64 + BPS_B

The above approach can provide BPS_B to accurately detect a flow rate of 5 mL/min, but it is very difficult to establish or simulated. Thus alternatively VFLWSENSE,no-fl w can be used in the equations to get another value of BPS_A and BPS_B. By adding an offset to BPS_B, a small flow can be detected.

Test Data

The following measurements were taken from the lab test system, with the data read directly by the data acquisition routine of a custom UCCOM program which allows a PC to communicate with a MISC I/O controller (no manual transcription involved except the external data which in this test is the flow rate), the data file is then imported to a spreadsheet for processing. In the following spreadsheet, the first three columns are data read directly from the controller, representing the temperature in hundredths of °C, and the numbers representing the sensing and the reference thermistor voltages, the "Flow" column is the flow rate as measured by a calibrated flow meter, manually entered at the time of data acquisition, the "Vflw0" column is the calculated values of flow threshold detection after BPS_A (=46.72) and BPS_B (=15032) are calculated with the 5 mL/min flow data at 21.95 and 40°C. The "FLOW" column results from the comparison between "Vflws" and "VFlw0", which is also done by the spreadsheet.
Averages:

Temp	Vflws	Vflwref	Flow	Vflw0		Temperature = 21.95		
2195	28841	17373	15	27716	FLOW			
2195	28960	17373	15	27716	FLOW	Flow	Vref	Vflws
2195	29066	17379	15	27720	FLOW	15	17375	28924
2195	28829	17376	15	27718	FLOW	10	17097	28470
2195	28439	17232	10	27613	FLOW	5	16694	27220
2195	28368	17112	10	27525	FLOW	0	16518	26408
2195	28465	17045	10	27476	FLOW			
2195	28607	16999	10	27443	FLOW			
2195	27187	16754	5	27264	NO FLOW			
2195	27308	16699	5	27224	FLOW			
2195	27129	16673	5	27205	NO FLOW			
2195	27256	16650	5	27188	FLOW			
2195	26542	16568	0	27128	NO FLOW			
2195	26380	16515	0	27089	NO FLOW			
2195	26372	16504	0	27081	NO FLOW			
2195	26338	16485	0	27067	NO FLOW			
Temp	Vflws	Vflwref	Flow	Vflw0		Temperature = 27.85		
2785	27429	14560	15	25662	FLOW			
2785	27491	14563	15	25664	FLOW	Flow	Vref	Vsens
2785	27137	14563	15	25664	FLOW	15	14561.5	27364.75
2785	27402	14560	15	25662	FLOW	10	14387.25	26877.5
2785	27005	14470	10	25596	FLOW	5	14127	25609.5
2785	26680	14378	10	25529	FLOW	0		
2785	26948	14365	10	25520	FLOW			
2785	26877	14336	10	25498	FLOW			
2785	25633	14180	5	25385	FLOW			
2785	25741	14136	5	25352	FLOW			
2785	25529	14112	5	25335	FLOW			
2785	25535	14080	5	25312	FLOW			
Temp	Vflws	Vflwref	Flow	Vflw0		Temperature = 31.675		
3163	26089	13019	15	24537	FLOW			
3163	26165	13017	15	24535	FLOW	Flow	Vref	Vsens
3163	26098	13021	15	24538	FLOW	15	13017.25	26175.25

Temp	Vflws	Vflwref	Flow	Vflw0		Flow	Vref	Vsens
3163	26349	13012	15	24532	FLOW	10	12863	25696.5
3169	25747	12932	10	24473	FLOW	5	12805	24690
3169	25688	12838	10	24405	FLOW	0	12781	24193.25
3169	25647	12832	10	24400	FLOW			
3169	25704	12850	10	24413	FLOW			
3169	24621	12832	5	24400	FLOW			
3169	24945	12818	5	24390	FLOW			
3169	24594	12800	5	24377	FLOW			
3169	24600	12770	5	24355	FLOW			
3169	24134	12768	0	24354	NO FLOW			
3169	24058	12797	0	24375	NO FLOW			
3169	23981	12789	0	24369	NO FLOW			
3169	24050	12742	0	24335	NO FLOW			

Temp Vflws Vflwref Flow Vflw0 Temperature = 34.175

Temp	Vflws	Vflwref	Flow	Vflw0		Flow	Vref	Vsens
3419	25415	12055	15	23833	FLOW			
3419	25547	12046	15	23826	FLOW			
3419	25596	12041	15	23823	FLOW	15	12043.5	25508.25
3419	25475	12032	15	23816	FLOW	10	11928.75	25111.5
3413	25096	11941	10	23750	FLOW	5	11832.75	24118.25
3413	25143	11936	10	23746	FLOW	0	12005.25	23541
3413	25158	11926	10	23739	FLOW			
3413	25049	11912	10	23729	FLOW			
3419	24181	11872	5	23699	FLOW			
3419	24235	11840	5	23676	FLOW			
3419	24020	11811	5	23655	FLOW			
3419	24037	11808	5	23653	FLOW			
3419	23606	12021	0	23808	NO FLOW			
3419	23523	12000	0	23793	NO FLOW			
3419	23520	12000	0	23793	NO FLOW			
3419	23515	12000	0	23793	NO FLOW			

Temp Vflws Vflwref Flow Vflw0 Temperature = 37.62

Temp	Vflws	Vflwref	Flow	Vflw0		Flow	Vref	Vsens
3759	24595	10816	15	22928	FLOW			
3759	24624	10841	15	22947	FLOW			
3759	24574	10816	15	22928	FLOW	15	10825	24572
3759	24495	10827	15	22936	FLOW	10	10774.75	24212
3759	24242	10784	10	22905	FLOW	5	10752	23277
3759	24255	10779	10	22901	FLOW	0	10786.5	22633.75
3759	24188	10763	10	22890	FLOW			
3759	24163	10773	10	22897	FLOW			
3765	23124	10752	5	22882	FLOW			
3765	23403	10752	5	22882	FLOW			
3765	23263	10752	5	22882	FLOW			
3765	23318	10752	5	22882	FLOW			
3765	22691	10816	0	22928	NO FLOW			
3765	22650	10816	0	22928	NO FLOW			
3765	22618	10808	0	22923	NO FLOW			
3765	22576	10706	0	22848	NO FLOW			

Temp Vflws Vflwref Flow Vflw0 Temperature = 40.0275

Temp	Vflws	Vflwref	Flow	Vflw0		Flow	Vref	Vsens
3996	23989	10077	15	22389	FLOW			
3996	24039	10057	15	22374	FLOW			
3996	23998	10060	15	22376	FLOW	15	10066	23979.75
3996	23893	10070	15	22384	FLOW	10	10019	23830.5
3996	23846	10016	10	22344	FLOW	5	10021	22348.5
3996	23827	10034	10	22357	FLOW	0	10077.5	22101.5
4002	23843	10013	10	22342	FLOW			
4002	23806	10013	10	22342	FLOW			
4008	22423	10048	5	22368	FLOW			
4008	22197	10016	5	22344	NO FLOW			
4008	22425	10016	5	22344	FLOW			

4008	22349	10004	5	22336	FLOW
4008	22191	10071	0	22385	NO FLOW
4008	22059	10077	0	22389	NO FLOW
4008	22058	10077	0	22389	NO FLOW
4008	22098	10085	0	22395	NO FLOW

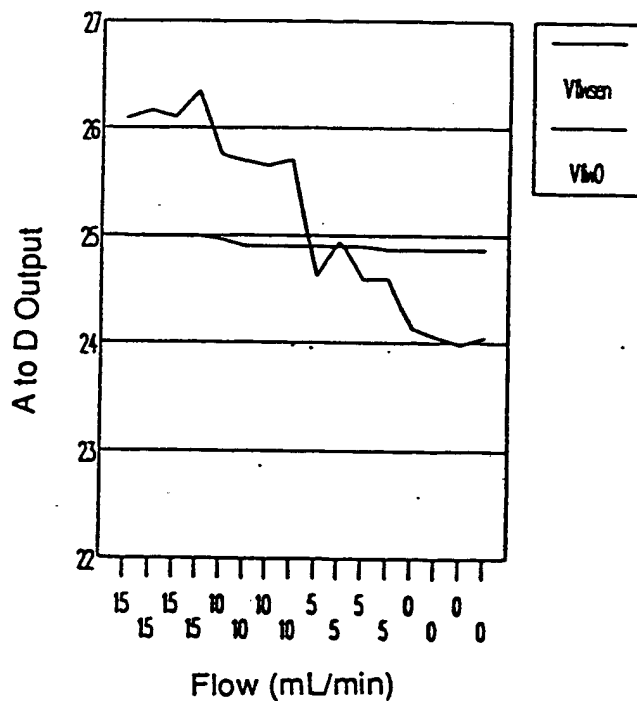The attached set of line-and-markers plots of the data illustrates the proper behavior of the flow detectors.

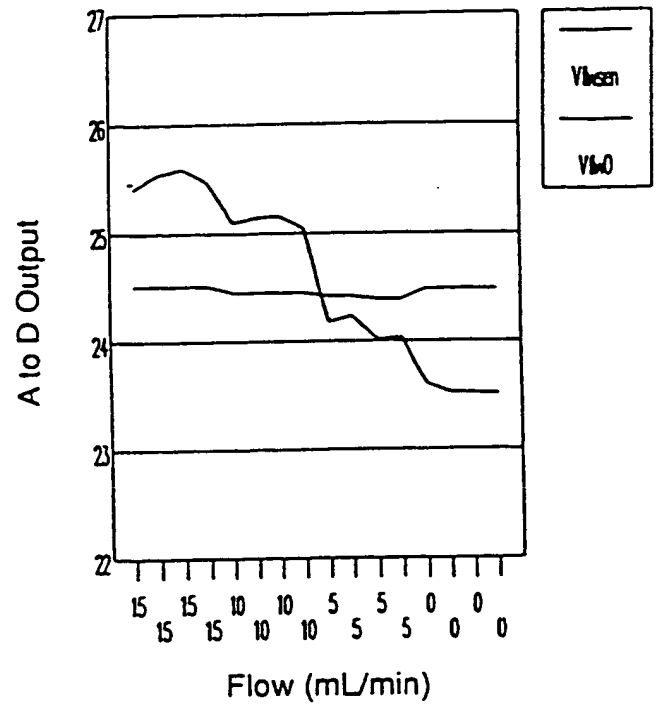## Vflwsen and Vflow0 vs Flow
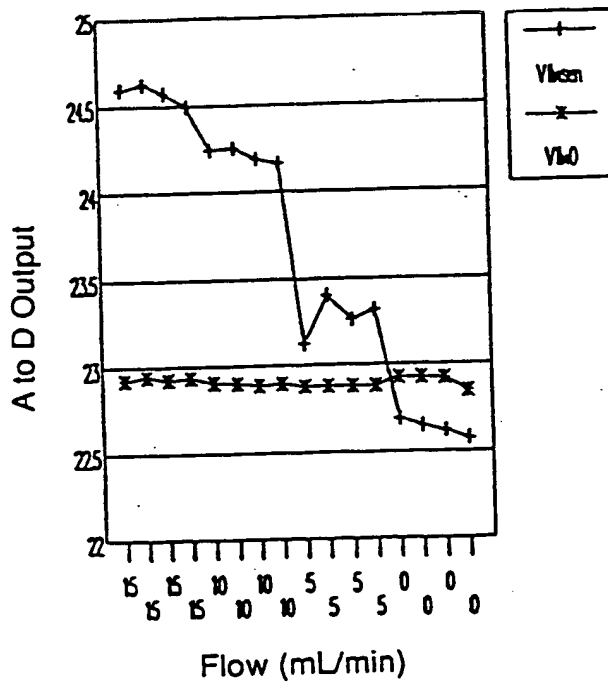
Tested at 21.95°C
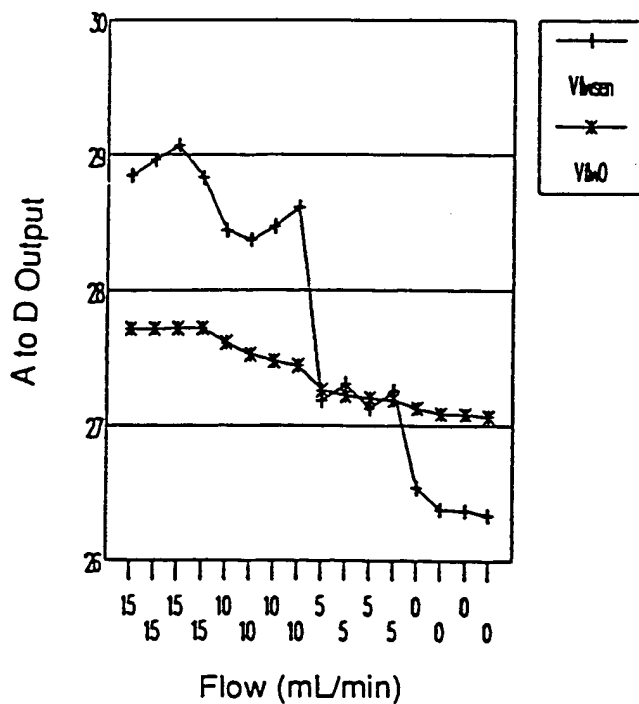
Vflwsen and Vflow0 vs Flow

Tested at 26.7°C

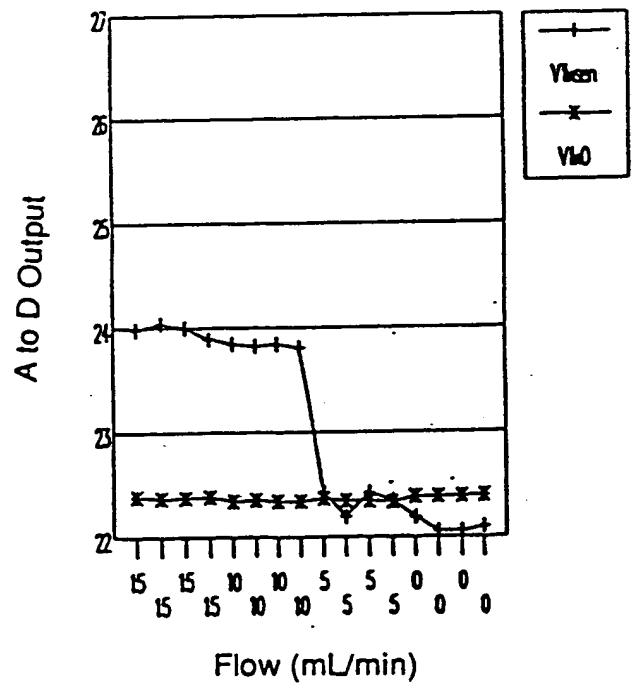## Vflwsen and Vflow0 vs Flow

Tested at 34.1°C

Vflwsen and Vflow0 vs Flow

Tested at 37.62°C

Vflwsen and Vflow0 vs Flow

Tested at 40°C

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Conclusion

From the test data, one can see that after the necessary calibration for the flow sensing thermistor, the flow sensing detection system gives correct indication of flow as low as 5 mL/min.

Air Detector

System Description

The purpose of the air detection system is to detect a 10 microliter air bubble in the venous blood line at different flow rates. When a bubble is detected during a dialysis treament, the stoppage of the blood pump and the clamping of the line clamp protect the patient.

The air detection system consists of a 2-MHz crystal-controlled oscillator driving a 2-MHz piezoelectric ultrasound transmitter. The ultrasound is transmitted through the blood tubing by means of an acrylic bumper, and again received by an identical piezoelectric ceramic transducer through an identical bumper. The received signal is amplified by two identical amplifiers to a detectable level of 1.5 to 5.5 V peak-to-peak, depending on the snugness of the mechanical contacts. The 2-MHz signal is then fed to a peak-to-peak detect r circuit in each channel to become a DC signal of 0.5 to 4.5 V. The peak-to-peak detector is inherently AC-coupled, resulting in a zero volt output in case of amplifier failure. A test input is provided to simulate an oscillator failure condition during Self Test. One of the two similar outputs of the detectors is fed into an A-to-D converter. A software routine periodically reads the level of the DC signal to compute a long term average level against which the instantaneous amplitude of the ultrasound level is compared to detect the presence of air bubbles. The time constant of the digital filter used in the computation of the detection level is 400 msec. Fifteen sixteenths of the average level minus 50 mV (for noise immunity) is used as detection threshold. Thus the software forms an automatic gain control to accommodate variations in the mechanical coupling of the 2-MHz ultrasound. The output of the comparator is read every 0.96 msec to detect the presence of an air bubble by effectively measuring the time the air bubble passes under the detection window. This time is compared to a host-programmable time which is a complex function of the flow rate, the diameter of the blood tube, and the size of the bubble to be detected. When the bubble time exceeds the programmed value, a software air alarm flag is set. In order to take into account many small bubbles equivalent to a large bubble, the software actually counts up by 16, until the programmed count limit is reached, when air is present under the detection window, and counts down by 1, with 0 being the lower limit, when no air is detected. Given the fact that air bubbles are only occasionally present, the count stays most of the time at zero.

The other detector output is fed to a bandpass filter to detect large air bubbles (300 microliters) as a backup. The output of this hardware air detector is latched so that it can clamp the blood line until reset by the host. A hardware air alarm bit is also set to inform the host of the alarm condition. Another comparator also sets the alarm bit and clamps the line clamp when a level of less than 0.5 V is put out by the peak-to-peak detector to indicate either a possible circuit failure or a large air gap, such as when the blood tubing is removed from the detector.

T st Set-Up

In order to check the correct operation of the air detection system, a water circuit with a Cole-Palmer NO44-40C flow meter, a DW thermometer #A-0097-0C-00, a calibrated syringe assembly to inject 10 µL bubbles one at a time, the air detector assembly connected to the I/O controller with its hardware and software, a fluid reserv ir with wrap-around heater, temperature sensor and control to keep the water temperature at 38°C, and finally a media pump capable of up to 1000 mL/min. The venous tubing going through the detector was of type B-D Drake-Willock #8881.

Test Procedure and Test Data

The fluid was circulated at 100 to 750 mL/min in 50 mL/min increments. A 10 uL air bubble generated by one turn on the syringe assembly knob was then injected into the flow path. The software parameter BBTIME was then varied to determine the detection threshold. At each flow rate, a photograph of the output of the comparator that the software strobes every 0.96 msec was taken so that the passage time of the bubble could be compared with the actual BBTIME by the formula INT(TIME/0.96)*16. This is because 0.96 msec is the sampling period of the software air detector and the software counts up by 16 every time air is present under the detection window as previously explained. Also because of the sampling mechanism, there may be a difference of 16 between BBTIME and the calculated value of BBCOUNT=INT(TIME/0.96)*16.

Alarm Flow mL/min	Calc Time ms	Test data BBCOUNT	BBTIME
100	88.5	1472	1300
150	36.2	592	620 *
200	21.1	336	330
250	16.1	256	250
300	10.2	160	150
350	9.35	144	125
400	7.75	128	120
450	6.95	112	112
500	6.35	96	98 *
550	5.8	96	96
600	6.2	96	96
650	5.8	96	96
700	5.65	80	96 *1
750	6.15	96	95

Notes: * denotes line in which the calculated BBCOUNT is less than BBTIME
*1 the value without integer truncating is 94.16667

It is observed that at low flow rate, the movement of the air bubble in the tubing is irregular, so that there are a lot of variations between test data for different trials. On the other hand, at high flow rate, the unexpected fluid dynamics make the detection time (the time the air bubble is seen under the detection window) virtually unchanged between 500 to 750 mL/min flow rates. The true relationship between the fluid flow rate and the speed of the air bubble in the vertically downward direction is obviously a function of fluid viscosity, the diameter of the tubing, the size of the air bubble, and the flow rate itself.

As to the three instances where BBCOUNT is less than BBTIME, a plausible explanation is in the limitations of th exp riment where not all the possible pictures were taken and c rrelated with the BBTIME data.

Another air detector assembly was built and tested. Measurements were made in the same test set-up as the previous test. A Tek type 464 oscilloscope was used instead of TEK-2221. Following are the test results:

| Flow Reading	Flow mtr #1	#2	#3	Avg	Detection times BBTIME	
100	10	12	140	120	126.7	2096
150	14	45	44	44	44.3	736
200	18	24	24	25	24.3	400
250	22	16	17	16.5	16.5	272
300	26	12	12.5	13	12.5	208
350	30	10.5	10	10.5	10.3	160
400	34	9	9.5	9	9.2	144
450	38	8	8	8.5	8.2	128
500	42	8.5	7.5	7	7.7	112
550	46	7	7.5	7.5	7.3	112
600	50	7	7	7	7.0	112
650	54	6.5	6.5	7	6.7	96
700	58	6	6.5	6	6.2	96
750	62	5.5	6	5.5	5.7	80

Flow in mL/min

Detection times in milliseconds

Flow meter readings were used to derive the flow rate.

A graphic comparison of the two test data is below.

Detection Time vs Flow
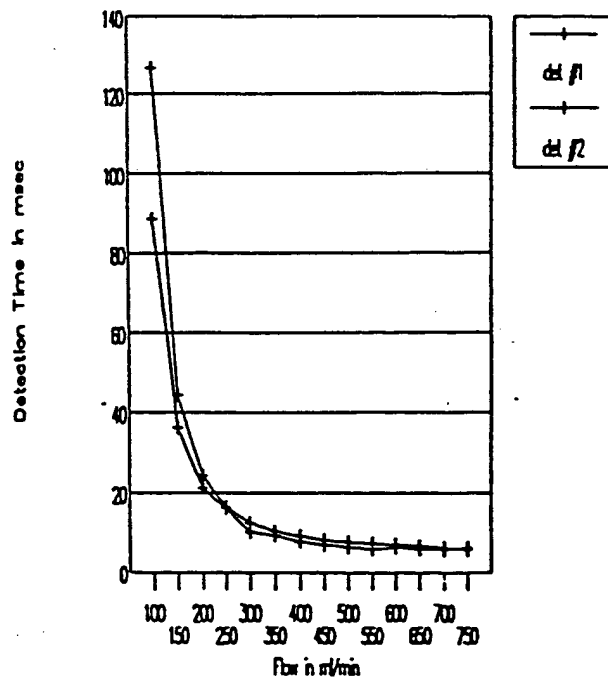
As one can see, the detection times are virtually the same in high flow rate but diverge at low flow rate. As explained earlier, this is due to irregularity in the movement of bubble in the tubing because of two opposing forces: the floating force tries to push the bubble up but the dragging force tries to pull the bubble along with the flow in the downward direction.

From the tests one can conclude that, in order to detect 10 uL air bubble in a tubing of 0.184 inch I.D., the parameter BBTIME should be set according to the last column (BBTIME) of the test data for the first detector assembly to be on the safe side.

Hardware Air Detector Sensitivity

In order to determine the threshold of detection of the hardware air detector with a blood flow rate of 500 mL/min, further tests with an improved test set-up were done. In this set-up, the blood line was bifurcated into two branches, one free-flowing, and one clamped so that an air bubble of any volume can be created by injecting air into the tubing with the aid of a syringe. Once the right amount of air is in the clamped tube and the measurement equipment ready, the clamp is released to let the bubble out. A venous tubing section (Drake Willock #8881) fitted with an air detector assembly from the monitoring machine #2 with downward flow was used to determine the detection sensitivity. Temperature- controlled water at 38°C was used in this test. The flow meter used was a Cole-Palmer NO44-40C with its accompanying calibration chart.

Experimental Results

Bubbles of 300 µL down to 150 µL consistently result in alarms. On the other hand bubbles of 50 µL result in no alarm. At 100 µL, they result in alarm almost half the time. Scope photos confirm that it takes a large enough bubble to result in a sufficient signal swing at the input of the comparator to reach the detection threshold. This is a direct result of the capacitive coupling of the signal and the RC filter network, which together form a bandpass filter. Thus the hardware air bubble detector is presently too sensitive (on the safe side). Further adjustments of the filter network will be done to set the detection threshold to 300 µL at 500 mL/min flow as per the specification.

Line Clamp

General

The LINE CLAMP DRIVER is a PWB assembly that, when its input is HIGH, will energize the solenoid to unclamp the blood tubing. Vice versa, when the input level is LOW or the inputs are not connected, the driver is not energized resulting in the solenoid in quiescent state and the blood tubing clamped.

The LINE CLAMP driver requires 120 ±2 Vac input and can be controlled by a TTL compatible signal at its logic input.

The driver when energized and in steady state is a constant current source, independent of the AC voltage variation within the specified range. In reality, the solenoid current is maintain d constant as long as there is sufficient voltage to perate the pulse-width modulator driving a FET as a switch.

When the UNCLAMP signal is first applied to the logic input, the FET switch is turned fully on for about 100 msec, resulting in a solenoid current of 1.5 to 2.5 A depending on the solenoid series resistance and the actual AC voltage. Then the current will decay down to a steady state current as the current feedback loop comes into action. The latter controls the duty cycle of the pulse-width modulator driving the FET on and off, resulting in an average steady state current of about 200 mA.

In order to minimize the clamp response time, a quick release circuit is added to the basic circuit to quickly dissipate the solenoid stored energy when the clamp signal is received. This added circuit does not by any means interfere with the pull-in or the normal operation of the line clamp.

The solenoid is equiped with a silicon rubber pad to attenuate the plunger-to-frame contact noise during pull-in. The thickness of this rubber pad as well as the hold current affect the clamp response time of the line clamp.

Test Data

Following are the test data related to the release time of the solenoid as a function of hold current and rubber pad thickness.

Hold current (mA)	Pad thickness (inches)	Time w/o quick release circuit (ms)	Time w/ quick release circuit (ms)
50	1/16	381	188
100	1/16	407	188
250	3/32	109	50
100	3/32	134 *	56 *

* data after 70,000 cycles to simulate pad compression.

The unclamp time is measured to be about 30 msec. At 200 mA hold current, thermal measurement shows that the solenoid case temperature rise is 20 to 22°C above ambient. At 300 mA hold current, the case temperature rise is about 30°C.

Life Test

Two line clamps and two pre-production line clamp drivers were put into life test to determine product life in an accelerated manner. The mechanical aspect of the test is subject of a separate report by the mechanical engineering group. In summary, the system under test went through a total of 500,000 cycles without any failure or malfunction.

Stress Analysis

Switching transistor

In the unclamp state, the current in the solenoid averages 200 mA and the duty cycle of the MOSFET (Q5) switch is about 10%. The transistor used (IRF733) has an ON resistance of 2.5 ohms. Thus the resistive loss in the transistor is 2.5*0.2*0.2*0.1= 0.01 W which is negligible. Assuming a typical DC voltage of 170 V, rise and fall times of 100 nses, the switching loss is calculated to be about 22 mW.

In the clamped state, the switching transistor is totally turned off and there is no heat dissipation.

During the pull-in period, the drain current is about 2 A for some 300 msec. Thus the energy loss in the transistor is about 2.5*2*2*.3 = 3 joules. As the unclamp action is very infrequent, there is virtually no thermal stress on the switching transistor Q5.

P wer resistors R15/R17

The peak DC voltage is 132*1.41 = 187V. Thus the power in the two power resistors is $(187-15)^2/5000$ = 5.92 W. Two 7-W power resistors are used, thus their derating is 5.92/14 = 0.42.

Quick-release zener D6.

The zener D6 absorbs the magnetic energy of the solenoid during its release. That energy amounts to $(5mH)*(0.2A)^2/2=.0001$ joules at each clamp action. This energy is too low to stress the zener diode D6.

Solenoid winding

The power dissipated in the solenoid in the unclamp state is 85*0.2*0.2=3.4W where 85 Ω is the resistance of the solenoid at ambient temperature. This is relatively a low power dissipation for a 2-inch diameter solenoid.

Audio Alarm Loudness

Purpose

The purpose of this test is to determine if the alarm transducer meets IEC 601-2-16 loudness specification of 65 dB at 1 meter.

Procedure

With the machine in an alarm condition and the speaker holes taped closed inside and out, monitor the audio output from a distance of 1 meter using a sound meter set for "FAST" response and "A" weighted. Measure from all four faces.

Equipment

Tripod and Tripod Adapter

Sound Meter: B&K Impulse Precision Sound Meter, Type 2209, D-9056-00-01

Conditions

Speaker and alarm transducer were mounted back to back and in the same plane as the blood pump power board. The speaker was facing down and the transducer up. The cabinet was closed and the 1 F cap used as the alarm power source was charged. The test area was free of hard walls and consisted of 5-ft office partitions configured as a narrow rectangle open at each end.

Additional Information

Cabinet material is 3/16 ABS.

Test Data

Front

65 to 66 dB - measured from the front center both with and without the speaker holes covered.

Right

74 dB - measured from the outside end of the dialyzer holder with a Freseneous F80 dialyzer in place.

Back

78 to 79 dB - measured from the hydraulics cover.

Left

70 to 74 dB - measured from the IV pole knob.

Six Minute Test

The machine was put in an alarm condition with the machine turned off (power fail). The audio intensity at the start of the test measured 66 dB. The audio intensity at the end of the six minutes was 65 dB. The observer's position relative to the sound intensity meter is critical and affects the test results. The sound intensity from the back of the machine measured 74 dB at the end of the six minutes.

Conclusion

The audio alarm loudness was measured to be higher or equal to the IEC specification in the four directions.

Audio Alarm sound levels

Data taken at 3 distances

Time in seconds

□ 1ft.   + 2ft.   ◇ 3ft.
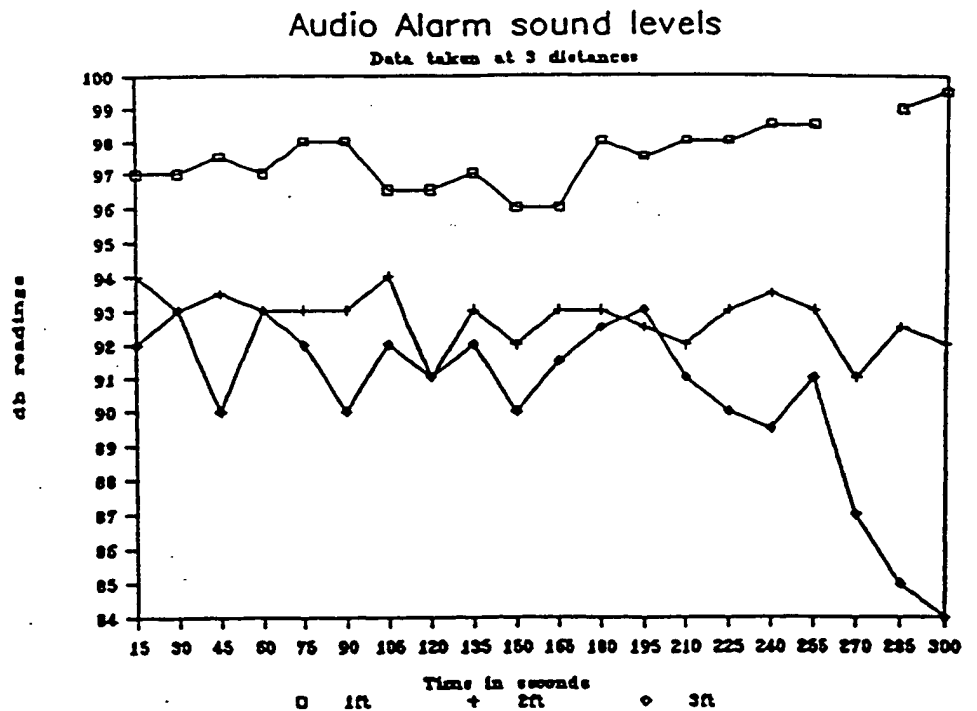
Pow r Fail Alarm Duration

Another test was set up to determine whether the duration of the alarm in a p wer fail situation is at least five minutes. In the three following tests, the microphone was placed at 1, 2, and 3 feet respectively from the transducer to determine whether any appreciable weakening of the sound level occurred as the energy storage capacitor was discharged.

The data show some variations in the sound level. This is due to the variations of the standing waves with the operator himself. On the average there is no appreciable sound level reduction after five minutes of testing in each case. However, the capacitor voltage did decrease from 5 V to about 4.33 V after five minutes of testing. If 2 V is the minimum operating voltage of the transducer, then by extrapolation of the discharge curve, one can say that the sound could last as long as 20 minutes. In reality, the transducer is capable of working down to 0.6 V, but with resulting reduced sound level.

Attached are the graphs showing the sound level and the capacitor voltage as functions of time for the three measurements.

Capacitor discharge rate
1 farad, audio alarm on
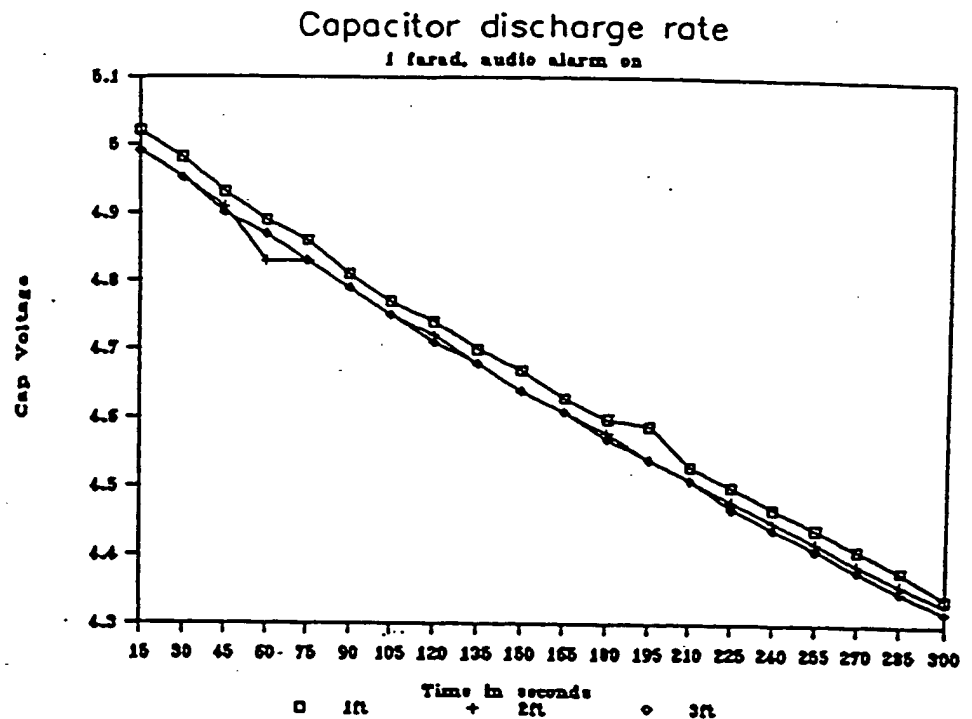
Power Supply Measurem nt Accuracy

General

The monitoring of the +5 V power supply uses a 10,000 and 15,000 ohm 1% precision voltage divider. The +12 V and –12 V power supplies are jointly monitored with a 15,000 and 24,300 ohm voltage divider.

Test Data

Actual	+12 V	12.06
Actual	–12 V	–12.20
Actual	+5 V	4.93

Signal	Reading	Cal	Meas'd	Ideal	Max	Min
VPS1(±12 V)	18048	2.7566	2.74	2.80	2.9147	2.6857
	17824	2.7224				
VPS2 (5 V)	19392	2.9619	2.96	2.96	2.9817	2.9343

The readings were taken from the display provided by a program on the PC which can read any memory location of the micro-controller. The calculated values are derived using the formula 5*Reading/32736. The 32736 value is the A-to-D number corresponding to 5 V, which results from the 10 bit A/D measurement being shifted left five binary positions. The measured values were obtained using a DVM. The ideal values correspond to the voltage divider output voltages actual power supply voltages. The maximum and minimum values correspond to worst case values of the resistors. One should note that while the VPS2 value is very constant, VPS1 fluctuates between the two recorded values.

Detection Threshold

Following are the calculations for different scenarios of the two +12 V and –12 V power supplies. One can see that only in the cases of a single power supply going too low that one can realistically detect the problem. If their magnitudes vary in the same percentage, the monitor voltage does not go out of the normal variation range to allow for accurate fault location.

	Nominal	Max	Min	12V–5%	–12V+5%	both–5%
V top	12.06	12.06	12.06	11.4	12	11.4
R top	15000	14850	15150	15000	15000	15000
R bottom	24300	24543	24057	24300	24300	24300
V bottom	–12.2	–12.2	–12.2	–12	–11.4	–11.4
Vmonitor	2.800	2.915	2.686	2.469	3.069	2.698

Conclusions

The test data show that the A-to-D conversion is highly accurate. An out-of-spec condition of the +5 V power supply can be easily detected. The detection of an out-of-spec condition of the +12 V or –12 V power supply can also be easily detected assuming that only one of the two supplies is out of specification.

Memory Board Circuit
Gen ral Description

The Memory board is an IBM PC/AT compatible board that provides the following:

6 ea.	28-pin EPROM sites (27512 (64Kx8) * 6 = 384 Kbytes)
1 ea.	28-pin CMOS RAM site (Dallas DS1225Y (8Kx8))
1 ea.	Dallas DS1287 AT compatible RealTime Clock module /w battery
1 ea.	NS16450 (NS8250 compatible) Asynchronous Serial Port
1 ea.	External Memory Card interface (uses external personality board)
1 ea.	Intel 8255 Programable Periphera! Inteface supports DS1287 RTC
	4 position DIP switch input
	Serial port & Ext. Memory Card configuration inputs
1 ea.	Scope trigger output for debugging support

Board Subsections

The board is divided into several major sections:

1. Root Level - Overall subsystem interconnection and PC Bus Buffers
2. PC Bus Connector
3. Board Control - General board control logic (also I/O Decoder)
4. Memory Array - EPROM & CMOS memory and support circuitry
5. External Memory Card Interface
6. External Memory Card Interface connector
7. Serial Port - Standard PC (NS8250 compatible) Serial Port
8. RealTime Clock - RTC & configuration inputs

Root Level

This is the root level sheet. It contains the PC Bus interface buffers and hierarchial interface to the lower level schematic sheets.

PC Bus control signal buffer IC

PC Bus Address buffers (also AEN control signal) ICs

PC Bus data buffer IC

Local data buffer for I/O mapped devices IC

Jumper for selecting Serial port interrupt

Jumper 1-2 for no interrupts

Jumper 1-3 for IRQ3 (COM2: use port address 02F8h)

Jumper 2-4 for IRQ4 (COM1: use port address 03F8h)

PC BUS Connector

This contains the actual PC Bus connector (P1) and the decoupling capacitors.

Board Control

This is the main control logic. It generates the signals that control the data buffers' direction and enabling. It also generates the PC Bus Wait States and decoding of I/O addresses.

Wait State Generator

This circuit is activated by any read or write operation of either memory or I/O as long as B_DACK0\ (buffered PC Bus DACK0\) is false (high). If B_DACK0\ is true (low) then the operation is a memory refresh operation which does not need (and should avoid) a wait state insertion.

Write DEN Stretchers

These circuits extend the trailing edge of the write strobes (for both memory and I/O) so that the data buffers remain enabled well beyond the end of the write PC Bus write strobes MEMW\ & IOW\. This is to meet the requirement to hold the data valid after the removal f the write strobe (most designs use the command strobes to enable the data buffers).

When a strobe goes true (low) it sets a flip-flop which generates a xxx_DATA_ENABLE signal. When the strobe is negated (goes high) the flip-flop remains set until the next rising edge of the PC Bus signal CLOCK.

A pair of NAND gates function as negative input OR gates to generate xxx_DATA_ENABLE signals for the memory & I/O address spaces. These are not gated by address decoding, requiring later logic to generate the final enable signals to the data buffers.

Buffer Direction Control

This is an R-S flip-flop that generates the data direction control signal (DT/R\) that is provided directly to the data direction control signal of all data buffers.

The flip-flop is always to the "write from CPU" direction prior to th leading edge of any strobe by the assertion of the PC Bus signal ALE. This ensures the earliest possible availability of data during a write operation.

DT/R\ = high => "WRITE from CPU to memory or I/O"

DT/R\ = low => "READ from CPU to memory or I/O"

I/O Command Delays

This circuit delays the leading edge of the I/O command strobes until the first rising edge of the PC Bus signal CLOCK after the command strobe has been asserted. The trailing edge of the command strobes are unchanged (other than propogation delays).

This provides additional address set-up prior to command assertion required by some I/O devices.

Not :   This circuit is similar but compl mentary to th "Write DEN Str tch rs".

Mem ry Buffer Control

This circuit generates address gated data nable signals to the memory devices' data buffers.

Board Data Buff r Control

This circuit is simply an AND gate used as a negative true input NOR gate. If any local data buffer is enabled the board's main data buffer is enabled.

I/O Decoder & Buffer Control

U14 is a PAL16L8 that combines the I/O address decoding functions and I/O buffer control functions. It also generates a fully decoded and gated signal DEBUG_TRIG\ to be used as a debugging aid.

The PAL design specification is in the file S2_IO_02.PDS. The signal B_AEN (buffered PC Bus AEN) must be false (low) to identify a bus cycle as a valid I/O operation rather than a DMA cycle. The signal B_IOW\ (buffered PC Bus IOW\) must be true (low) to activate the DEBUG_TRIG\ signal, it has no other use in this PAL.

The signal I/O_DATA_ENABLE (high true) is used to gate with valid I/O address to enable the IO_BUF_EN\ signal which enables the local I/O data buffer (U6, sheet 1). The signals CLOCK_CS\ & SERIAL_CS\ (both low true) are the fully decoded chip select signals to U38-6 & U33-14, respectively.

Memory Array

The Memory array is isolated from the main address bus by 74LS244 octal buffers and from the main data bus by a 74LS245 bi-directional octal buffer.

CONTROL LOGIC : The chip decoding is implemented with a PAL16L8.

A jumper (JP5) provides the capability of selecting an alternate memory map for development purposes. During normal operation, the jumper is either removed or placed on pins 2-3. This allows production units to be built without JP5 installed. The pull-up resistor (R13) is always required.

The outputs of the PAL are six chip selects for the EPROM's, a chip select for the Non-volatile CMOS RAM, and a chip select for the External Memory Card. A 74LS30 eight input NAND gate is used as a low true input OR gate to generate the signal MEM_SEL that is used by the Memory Buffer Control logic to enable the memory aray & main board data buffers.

External Memory Card Interface

This consists primarily of address & data buffers for the External Memory Card interface.

This circuit is connected to an external Parsonality board with the actual memory card connector and additional buffering. The CARD_xxxx signals (from sheet 6) are dependent on the particular personality board installed. They can be read by the CPU to determine the type and status f the External Memory Card.

The enabling of the address & control signal buffers (U28, U29, U30) is normally controlled by the personality board for the External Memory Card. A jumper (JP6) is provided for manually forcing the enabling of the buffers. The jumper (JP6) is n t necessary for production units. The pull-up resistor (R14) is always required.

External Memory Card Interface Connector

This is the physical connection for the External Memory Card (P 2) and the Serial Port (P 4).

Serial Port

The Serial Port is a fully PC compatible serial port using a National NS16450 chip which is a superset of the National NS8250.

The signals are buffered with standard TTL buffers. The actual drivers/ receivers (RS-232 or RS-485) are on a small external board that also includes the appropriate connector and optical isolation.

Real Time Clock

The Dallas Semiconductor DS1287Y Real Time Clock module (U39) has an on-board crystal and lithium battery. It also includes an Intel 8255 Programable Peripheral Interface to support the DS1287Y and to read the status/configuration information from the DIP switches (SW1), the External Memory Card, and the Serial Port buffer/ isolation board.

The 8255 is used to implement a "virtual bus" to interface to the DS1287Y because the DS1287Y is unable to operate at the full PC Bus speed. Port A of the 8255 is used as a bi-directional data bus and the upper half of port C is used to generate the control signals (the DS1287Y is configured, by the grounding of pin 1, to operate with Intel style control signals).

Unfortunately, the 8255 has the characteristic that any time the mode of any port is changed (in this case to change the data direction of port A) all outputs of all ports are set to low. Additionally, at reset or power-up, all ports are set to inputs and allowed to float high. This requires that all circuitry attached to the 8255 must be able to accept outputs that may be both all low or all high. This required the addition of a package of NAND gates (74LS00) between port C of the 8255 and the control inputs of the DS1287Y to allow proper opeeration of the DS1287Y.

Modification

The modification inverts the 8255 outputs PC.5 & PC.4 before they are applied to the RD\ & WR\ (respectively) inputs of the DS1287. These signals are also gated with the inverse of PC.6 (which, uninverted, provides the CS\ signal to the DS1287). This combination prevents the assertion (low) of the DS1287 RD\ & WR\ signals at the same time (which is an illegal operation) for both the power-up/reset condition of all 8255 outputs high and the condition of all 8255 outputs low when the direction of 8255 port A is reversed. The last gate of the 74LS00 package is used to invert the high true B_RESET signal and apply it to the DS1287.

Timing Analysis

Access/Setup times are determined by the PC Bus clock speed, PC Motherboard propogation delays, PC interface board pr pogation delays, and the number f inserted wait states.

CPU Access/Setup Times

There are two data access times that must be considered :

1 . Address to data

2 . Command Strobe to data

The worst case must always be used.

All times assume zero inserted wait states. If N wait states are inserted the Access/Setup times will be increased by N CPU clock cycles Tcy.

CPU Timings

All times are the same for both Memory and I/O transfers. All times are worst case.

80XX	Symbol Parameter	5 MHz	8 MHz	10 MHz
Tcy	CLK Cycle Period	200 nS	125 nS	100 nS
Tclav	Address Valid Delay	110 nS	60 nS	50 nS
Tdvcl	Data in Setup Time	30 nS	20 nS	5 nS
Tcldx	Data in Hold Time	10 nS	10 nS	10 nS
Tcldv	Data out Valid Delay	110 nS	60 nS	50 nS
Tchdx	Data out Hold Time	10 nS	10 nS	10 nS

8288	Symbol Parameter	not specified by CPU clock speed
Tclml	Command Active Delay	35 nS
Tclmh	Command Inactive Delay	45 nS

References : 5 MHz & 8 MHz - Intel 1988
10 MHz   - Siemens SAB8086

Read Data Access

The data is sampled by the CPU at the begining (CLK falling, high to low) of the CPU T4 clock cycle. There is a required setup time of Tdvcl and a required hold time of Tcldx.

Write Data Setup

The data is available from the CPU at the begining (CLK falling, high to low) of the CPU T2 clock cycle, after the Tcldv dealy. The data remains valid until the middle (CLK rising, low to high) of the CPU T4 clock cycle.

Address to Data

The address is made available at the begining (CLK falling, high to low) of the CPU T1 clock cycle after the delay Tclav.

Addr. Read Access = (3 * Tcy) − Tclav − Tdvcl
Addr. Write Setup = Tcy − Tclav + Tcldv

	5 MHz	8 MHz	10 MHz
(3 * Tcy)	600 nS	375 nS	300 nS
Tclav	110 nS	60 nS	50 nS
Tdvcl	30 nS	20 nS	5 nS
Addr. Read Access ▪	460 nS	295 nS	245 nS

	5 MHz	8 MHz	10 MHz
Tcy	200 nS	125 nS	100 nS
Tclav	110 nS	60 nS	50 nS
+ Tcldv	110 nS	60 nS	50 nS
Addr. Write Setup ▪	200 nS	125 nS	100 nS

Command Strobe to Data

Command Strobes are generated by the 8288 Bus Controller.

The Command Strobes are asserted at the begining (CLK falling, high to low) of the CPU T2 clock cycle after the delay Tclml.

Cmd. Read Access ▪ (2 * Tcy) – Tclml – Tdvcl

Cmd. Write Setup ▪ – Tclml + Tcldv

	5 MHz	8 MHz	10 MHz
(2 * Tcy)	400 nS	250 nS	100 nS
Tclml	35 nS	35 nS	35 nS
Tdvcl	30 nS	20 nS	5 nS
Cmd. Read Access ▪			

	5 MHz	8 MHz	10 MHz
Tclml	35 nS	35 nS	35 nS
+ Tcldv	110 nS	60 nS	50 nS
Cmd. Write Setup ▪	75 nS	25 nS	15 nS

PC Bus Access/Setup Times

PC Bus (Read) Access Time is the time from the assertion of the command strobe (MEMR\, MEMW\, IOR\, IOW\) on the PC Bus until the data from the PC interface board is stable on the data lines of the PC Bus.

PC Bus (Write) Setup Time is the time from the assertion of the command strobe on the PC Bus until the data from the PC interface board is stable on the data lines of the PC Bus.

NOTE : The following description of the PC Motherboard implementation refers only to the DTK Model PIM-TB10-Z.

Command Strobes & Clock

The PC Bus command strobes (MEMR\, MEMW\, IOR\, IOW\) are directly driven on the PC Bus by an 8288 Bus Controller. The data bus of the 80XX CPU is isolated from the PC Bus data lines by a 74LS245 (U23) octal transceiver. Therfore, the PC Bus Access & Setup time are calculated from the data sheets for the 80XX CPU & 8288 Bus Controller, subtracting the propogation delay of the 74LS245 buffer (12 nS typical, 18 nS maximum re: TI TTL Data vol 2, 1985).

The skew & propogation delays between the 80XX CPU, 8284 Bus Controller, and the PC Bus must also be considered. The 80XX & 8288 are physically connected directly to the CLK output of the 8284 Clock Generator (U91-8). This clock signal is buffered from the PC

Bus by a 74LS244 (U17-17->3) (12 nS typical, 18 nS maximum re: TI TTL Data vol 2, 1985). This shortens the apparent delay from the PC Bus CLK (B20) transitions to the change f the PC Bus command strobes' state.

The CRITICAL FACTOR for read access times is the state of the data at the 80XX CPU's data pins with respect to the clock signal at the 80XX CPU's CLK (19) pin.

Another factor (that actually improves the situation) is that if the interface is designed correctly (the Chip Select signals are derived exclusively from the contents of the PC Bus address lines, and NOT gated by a command strobe) the access time from address to data is not affected by the command strobes. The command strobes affect the access time from command assertion to data output enable (which is generally shorter that address to data).

The PC Bus command strobes from the 8288 are identical with respect to the CPU clock and CPU bus cycle states. All further references to "command strobes" apply to all of the PC Bus command strobes.

The command strobes are change state when the CLK signal falls from high to low. The I/O_CH_READY PC Bus (A10) is sampled on the first falling edge of CLK after the command strobe has been asserted.

NOTE : The DTK model PIM-TB10-Z PC clone has some strange Ready logic.

Data Path

The 80XX CPU data bus is buffered from the PC Bus data lines by a 74LS245 (U23). The propogation delay of the 74LS245 (8 nsec typical, 12 nsec maximum, re: TI TTL Data vol2, 1985) must be included in the calulations.

Read Data Sampling

The read data is sampled by the 80XX CPU on the same falling (high to low) edge of the CLK signal that causes the command signal to go false.

		5 MHz	8 MHz	10MHz
Tdvcl	Data In Setup		30	20
Tcldx	Data In Hold		10	10

Write Data Availablilty

The write data is available from the 80XX CPU after the same falling (high to low) edge of the CLK signal that causes the command strobe to go true. The write data is held valid by the 80XX CPU until after the rising (low to high) edge of the CLK after the command strobe goes false.

		5 MHz	8 MHz	10 MHz
Tcldv	Data Valid Delay		110	60
Tchdx	Data Hold		10	10

```
PC Bus                      8288
MEMW\ ( B11 )               AMWC\ ( 8 )
MEMR\ ( B12 )               MRDC\ ( 7 )
IOW\ ( B13 )                AIOWC\ ( 12 )
IOR\ ( B14 )                IORC\ ( 13 )
CLOCK ( B20 )               CLK  ( 2 ) buffered by 74LS244
ALE  ( B28 )                ALE  ( 5 )


5 MHz = 80C88AL
8 MHz = 80C88AL-2
```

NOTE : The 8288 Bus Controller generates two additional command strob s,
        MWTC\ (8288-9) & IOWC\ (8288-11). These are identical to AMWC\ &
        AIOWC\, respectively, except that they are asserted exactly one full
        CPU clock cycle later. These signals are not used in the PC Bus
        environment.

General Access Times

There are two possible limiting foctors for Access/Setup times :

1. Address to data

2. Command to data

Each must be calculated and the Access/Setup time is the worst of the two.

EPROM Memory Array Access/Setup Times

```
Address to Data
Early Address Availability  - ? nS
Board Address Buffers       74LS244     18 nS
Array Address Buffers       74LS244     18 nS
EPROM Addresss to Data 27512-25         250 nS
Array Address Buffer        74LS245     12 nS
Board Address Buffer        74LS245     12 nS
```
Note: ALE gating of Chip Select causes unneeded delay
```
Command to Data
Board Command Buffer        74LS244     18 nS
EPROM Output Enable to Data 27512-25    100 nS
Array Address Buffer        74LS245     12 nS
Board Address Buffer        74LS245     12 nS
```

Miscellaneous Design Issues

Bus Capacitive Loadings

Address

```
Main Internal Address Bus - A_D[0..7] :
5 pf      74LS244     U4 (U3, U2)  Board buffer ( BUS DRIVERS )
4 pf      PAL16L8     U14          I/O Decoder
5 pf      74LS244     U16 (U15)    Memory Array buffer
4 pf      PAL16L8     U18          Memory Decoder
5 pf      74LS244     U30 (U29, U28) External Memory Card buffer
10 pf     NS16450     U33          Asynchronous Serial Port
10 pf     8255        U38          Programable Peripheral Interface


Memory Address Bus - A[0..7] :
5 pf      74LS244     U16 (U15)    Memory Array buffer
36 pf     27512       U20-U25      EPROM ( 6 * 6 pf )
10 pf     DS1225      U27          N nVolatil  RAM module
```

Data

```
Main Int rnal Data Bus - B_D[0..7] :
6.5 pf      74LS245     U5        Board Buffer
6.5 pf      74LS245     U6        I/O Data Bus Buffer
6.5 pf      74LS245     U17       Memory Buffer
6.5 pf      74LS245     U31       External Mem ry Buffer

I/O Data Bus - IOD[0..7] :
6.5 pf      74LS245     U6        I/O Data Bus Buffer
20 pf       NS16450     U33       Asynchronous Serial Port
20 pf       8255        U38       Programable Peripheral Interface

Memory Data Bus - D[0..7] :
6.5 pf      74LS245     U17       Memory Buffer
72 pf       27512       U20-U25   EPROM ( 6 * 12 pf )
10 pf       DS1225      U27       NonVolatile RAM module
```

Safety Verify Functions

Description

The System 1000 Safety Verify Functions include functions which alert the operator of a safety system failure and take necessary the action to prevent immediate patient injury.

Safety systems are those which protect the patient from unsafe conditions that may occur during a normal dialysis treatment. The Safety Verify Functions include:

1. System hardware watchdog
2. Interprocessor communication verification
3. Bypass failure alarm
4. System selftests
5. Blood pump failure alarms

Test Data

System Hardware Watchdog

The hardware watchdog is located on the Misc I/O Controller board, and must have its input toggled by the Misc I/O Controller periodically to prevent it from activating the system Shutdown line. An activated Shutdown line forces the machine into an inoperable yet safe condition.

Tests were performed to determine the watchdog's timeout time, and to ensure that a shutdown condition resulted when its input was no longer toggled. The test was conducted by setting the CTRL_WATCHDOG bit of the Misc I/O Controller's CONTROL variable, which disables the toggling of the watchdog input.

Test results showed the normal watchdog toggle rate to be approximately 1 KHz, and the watchdog timeout period was about 1.5 seconds. The activation of the shutdown line was verified.

Interprocessor Communicati n Integrity

To ensure that the machine is placed in a safe operating condition in the event that the main 80XX controller fails, the three microcontrollers that it communicates with require constant servicing. If the 80XX fails to communicate with one of the microcontrollers within a specified time period, the microcontroller will activate the system shutdown line. This function is disabled on each microcontroller board if the board's JP4 test jumper is installed.

This function was tested on each of the three microcontroller boards, both with and without the JP4 jumper installed. On 5/7/90 in the integration prototype machine the Blood Pump Controller (software version 21.4) and the UF Controller (software version 1.7) were tested. Neither activated the shutdown line with their respective jumpers installed. With the jumpers removed, each activated shutdown after 10 seconds from the time that communication with the host 80XX was terminated. The Misc I/O Controller was tested on 5/14 (software version 8.0). No shutdown occured with the jumper installed, while after 6 seconds of no host communication the shutdown line was activated.

If one of the microcontrollers fail to respond to the host during communication, the host initiates a system shutdown. This was tested by forcing the reset pin of the UF Controller to ground for a sustained period of time. Within a couple of seconds, the host displayed both "Controller error at UF com port" followed by "No UF response... port terminated", with a shutdown condition resulting.

Bypass Fail Alarm

The bypass fail alarm is based on the intended state of the bypass valve, and whether dialysate flow is detected by a thermal flow detector located between the bypass valve and the dialyzer. If the bypass valve is commanded to bypass the dialyzer flow circuit, and the flow sensor detects flow, then a bypass fail alarm results. This alarm results in a machine shutdown condition.

This alarm was tested by shorting the bypass valve driver (Q8) on the Misc I/O Hydraulics Power board, which forced the bypass valve into the non bypass state. When the machine was powered up and left in Standby mode, the bypass fail alarm occured within 30 seconds.

In addition, with this simulated failure, a bypass fail alarm resulted during the conductivity alarm self test two out of three times (one time a self test failure resulted first).

Self Test

The following self tests are performed by the first clinical monitoring version of the System 1000 machine:

Arterial/Venous Pressure Test

Verifies operation of the high and low arterial and venous pressure alarms, the level adjust system, and the relative accuracy of the arterial and venous pressure measurements. Verifies operation of the audible alarm and main alarm lamp.

Blood Leak D tector T st

Verifies the operation of the blood leak detector.

UF Test

Verifies operation of the UF removal metering device, tests for leaks in the UF system, and verifies the operation of the high and low TMP alarms.

Temperature Alarm Test

Verifies the operation of the dialysate temperature alarms, which include the primary high and low alarms and the redundant high alarm.

Conductivity Alarm Test

Verifies the operation of the dialysate conductivity alarms, which include the ±5% primary high and low alarms, the A and B part redundant high and low alarms, and the fixed backup high and low alarms.

Air Detector Test

Verifies the operation of the primary (software) air detector alarm and the backup (hardware alarm).

Conductivity Verify Test

Asks the operator to verify the primary conductivity measurement, and then calculates the primary limits around this value. Also verifies that the A and B part conductivity measurements are reasonable, and then sets the redundant limits around these values.

Test Data

Each of these self tests was verified by simulating a failure condition of the function being tested and confirming that a self test failure resulted. A self test failure ensures patient safety by preventing the machine's Prime or Dialyze mode from being entered. The following details the simulated failure used for each test, along with the resulting failure message that was displayed.

Arterial/Venous Pressure Test

The venous pressure luer was not plugged as is required for the test. This prevented the venous pressure from being pumped above its upper limit, and resulted in the following error message: "Bld Press Test: No high ven." This simulated either a level adjust failure or a venous pressure measurement failure.

This test was repeated with the arterial pressure luer not plugged, with the following error message resulting: "Bld Press Test: No high art".

The calibration of the arterial pressure was then offset so that the measured pressure was 60 mmHg at atmospheric pressure. The self test then reported: "Bld Press Test: No press match." This simulated a pressure measurement accuracy failure.

Blood Leak D tector T st

For this test a simulated bl od leak detector was used, consisting of the LED and photocell assemblies used in the actual detector, coupled together inside an opaque tube. The LED and photocell were first pulled apart to the extremes of the tube (appr ximately three inches) and the blood leak system was calibrated. It was verified that the blood leak detector self test successfully passed. The LED and photocell were then repositioned closer together (about one inch apart). This time the self test reported: "Blood Leak Fail: No alarm." This test simulated a failure caused by either an increase in the LED intensity or a decrease in the photocell resistance.

UF Test

The test was verified on a machine with flow path problems that prevented it from building any dialysate pressure when the UF removal metering device was run. The following error message resulted: "UF Tst: TMP Not In Range".

Temperature Alarm Test

This test was not verified because of the difficulty involved in simulating a failure. The self test verifies these alarms by momentarily changing the alarm limits to force an alarm based on the currently measured temperature value. The high temperature alarm test included in the Conductivity Alarm Test was tested however (refer to the next section).

Conductivity Alarm Test

The hardware test line which forces the primary conductivity amplifier to output a high value was defeated with a clip lead (pin 20 of U26 on the Misc I/O Controller board was shorted to ground). The following error message resulted: "Cond Test: High Alarm Failed." This simulated a primary conductivity circuit failure.

The hardware test line referred to in the previous paragraph also forces a primary high temperature alarm, however since the conductivity alarm is tested first, if it fails the temperature alarm is never tested. Therefore just the high temperature alarm test was defeated by disconnecting the output of the comparator which shunts the temperature measuring thermistor during the self- test (pin 1 of U14 on the Misc I/O Hydraulics Power board). This resulted in the following message: "Cond Test: Hi Temp Alarm Failed." This simulated a primary temperature circuit failure.

Since the redundant conductivity self test verifies that there is no dialysate flow during the alarm, a bypass valve failure was simulated by shorting the bypass valve driver on the Misc I/O Hydraulics Power board (Q8). The conductivity self test was run three times with this failure mode, one time resulting in the following error message: "Cond Tst: Redundnt Hi Alm Failed." The other two times resulted in a Bypass Fail alarm, with a machine shutdown resulting.

Air Detector Test

The primary (software) air alarm was disabled by shorting the output capacitor of the primary ultrasonic receiver amplifier (C6 on the Misc I/O Electrical Power board). This resulted in the f llowing message: "Air Fail: No soft alarm".

The backup (hardware) air alarm was then disabled by shorting the output capacitor of the backup ultrasonic receiver amplifier (C8 on the Misc I/O Electrical Power board). This resulted in the following message: "Air Fail: No line clamp".

C nductivity V rify Test

The machine was run in bicarb mode (bicarb concentrate line not on rinse fitting), with resistors used for the conductivity probes to simulate normal bicarb conductivities (8 mS/cm for the A probe, 13 mS/cm for the B probe). With this arrangement, the conductivity verify test successfully passed. Then the resistors for the A and B probes were reversed (A now measuring 13 mS/cm and B measuring 8 mS/cm). The following error message resulted: "Cond Verify Error".

Blood Pump Failure Alarms

The blood pump failure alarms consist of the Blood Pump Stop alarm and the Blood Pump Overspeed alarm. The Stop alarm occurs after 30 seconds from the time when the pump stops turning if the host has not commanded the pump to stop. This situation can exist if the blood pump drive circuit fails, the blood pump door is opened, or the blood pump is turned off by the Blood Pump controller because of an overspeed condition. The Overspeed alarm occurs if the controller detects the pump running at a faster rate than is expected. The controller uses two independent methods for determining pump speed: an optical tach signal, and the motor's back EMF voltage. An overspeed condition can result if the tach signal is lost (using the EMF voltage as an indication), or if the motor drive circuit fails.

The Blood Pump Stop alarm was tested by running the blood pump in Dialyze mode, and unplugging the tach signal/door switch connector (JP2) on the Blood Pump Power board. This effectively opened the door switch, which caused the controller to stop the pump. After approximately 30 seconds an alarm resulted, with the message "Blood Pump Stop Alarm" being displayed in the error window, and the audio alarm and the main alarm lamp being activated.

The Blood Pump Overspeed alarm was tested with three different failure modes: a complete loss of the tach signal, a partial loss of the tach signal (with one of the motor shaft holes plugged), and a drive circuit failure resulting in full power being applied to the motor.

The loss of the tach signal failure was created by removing the tach sensor assembly from the rear of the motor. This failure was tested both while the motor was running at 200 RPM and from initial pump turn on. When the failure occured while the pump was running, the pump began running at high speed for approximately two seconds before turning off with the message "Blood Pump Over Speed Alarm" being displayed in the error window. When the failure occured while the pump was turned off, then after the pump was turned on it ran at high speed for approximately four seconds until turning off with the same message. In both cases, after about 30 seconds from the time that the motor was turned off, a Blood Pump Stop Alarm occured.

The partial loss of tach signal failure was created by taping over one of the two holes on the motor shaft used for tach sensing. This effectively caused the motor to run at twice the desired speed, and relied upon the back EMF sensing to trigger the alarm. From motor

turn on, within four s conds the motor turned ff with "Blood Pump Over Speed Alarm" being displayed. Thirty seconds after the pump stopped a Blood Pump Stop alarm resulted.

The drive circuit failure was created by shorting the utput of the pulse width modulator (Pin 1 of U2 n the Blood Pump Power board) to ground. This failure was created both while the motor was running at approximately 200 mL/min and while the motor was off. In both cases, the failure caused the motor to immediately run at high speed, and after approximately four seconds the motor stopped due to a machine shutdown condition. The messages "Bld Pmp Overspeed Alarm" and "BP Control Shutdown" were displayed in the error window.

Summary

The Safety Verify Functions monitor critical system functions and provide indication of and machine response to hardware failures that could cause patient injury. These failures include those that could disable the primary safety alarms (e.g. dialysate and extracorporeal alarms), as well as others that could result in immediate patient risk (e.g. bypass fail alarm).

The Safety Verify Functions were tested by simulating hardware or calibration failures, and verifying the expected results. All functi ns tested were verified to be effective at identifying the simulated failures.

Power Supply System

Introduction

The System 1000 is meant to be operated off line power at 100, 120, 200, 220 or 240 volts AC determined by a voltage selector switch, at 50 or 60 Hertz. Input protection is provided by a 20 amp circuit breaker when operated from 120 volts. Power is supplied to the system in two forms; transformer isolated with multiple voltage taps and non-isolated line voltage.

The non-isolated power is provided for the dialysate heater circuit and is switched by means of a solid state relay.

Isolated power is provided for all other requirements including the system +24 volt, +5 volts, +12 volts and –12 volt DC supplies.

Isolation Transformer

Power isolation is provided by a purchased transformer specified with 4000 volts RMS input to output isolation. Isolated power is provided as 21 volts AC for the system unregulated 24 volt DC supply, as 120 AC to the system switching power supply and as 20 volts AC which is specified to be isolated (4000 volts RMS) from the other secondaries and may be used with auxiliary circuits to be connect to other equipment. In addition to providing high voltage isolation the transformer design is important in meeting equipment leakage current specifications (typically 100 micro-amp chassis).

Testing Data

Transformer leakage current (120 VAC applied):

3.5 uA forward;

3.0 uA reverse.

Transformer isolation (hi-pot.):

Tested 3 KV between primaries and secondaries, tested 3 KV between auxiliary power secondary and other secondaries, 600 V between all secondaries. Isolation was maintained during all tests (no voltage breakdown).

Transformer outputs:

24 volt supply load regulation (1 amp to 10 amp loading at power supply board): 9%, with measured output voltages of 28.3 VDC and 25.7 VDC (V primary = 118).

20 VAC Auxiliary power maintains 20.9 VAC with a 0.19 A load (V primary = 117).

120 VAC supply (switching power supply loaded 100 watts):

maintains 123 VAC output (Vprimary = 117).

Temperature rise:

19°C without load;

32°C full load (24V @10A, 20VAC @0.25A, 120VAC @1A).

Switching Power Supply

A commercial power supply is used to provide +5, +12 and –12 volt regulated power to the system.

Test Data

OUTPUTS	MAX. LOADS as tested	LOAD REG.
+5 V	10 amps	0.00%
+12 V	1.5 amps	0.08%
12 V	1.0 amps	0.08%

Line regulation was less than 0.1% tested at 85 and 132 VAC.

Power Loads Test Data

Non-Isolated Line Voltage

The only non-isolated power load is the dialysate heater. The heater element is available as 100, 120, 200, 220 and 240 volt options. The power specification for the elements is 1500 watts ±5%. The thermostat and all associated wiring is adequately rated for this load.

24 VOLT LOADS

Blood Pump Sub System	Current in Amperes
Blood Pump motor (with tubing,500 mL/min flow)	1.40
Heparin Pump (Type C)	0.360
Level Adjust motor (Type A)	0.330
Level Adjust valves (Type CM)	0.040
Fan (Innovative)	0.21
Blood Pump Power total	2.34

UF Power Sub System   **Current in Amperes**

Flow Equal. valves (Type M 4 on)	1.56
UF Removal Valves (Type M 1 on)	0.390
Rinse Valve (Type MS)	0.10
Proportioning pumps (Type V PH268-23 2 on)	1.16
Proportioning valves (Type M 2 on)	0.780
UF Power total	3.99

I/O Sub System   **Current in Amperes**

CRT (Type C B/W)	1.18
ON/OFF valve (Type S)	0.30
Bypass valve (Type S)	0.30
Supply Pump (Type M @ 500mL/mi.)	0.390
De-air/air Pump (Type M @ 500mL/min)	0.840
I/O total	3.01

           Current in Amperes

24 VOLT SYSTEM TOTAL	9.34

All above measured at nominal line voltage.

PCB LOADS +5VDC, +12VDC AND -12VDC Measured

	+5	+12	-12
BLD PUMP CONT.	0.251	0.0242	0.0163
BLD PUMP POWER	0.065	0.0963	0.0002
UF CONTROLLER	0.220	0.0244	0.0164
UF POWER	0.068	0.0483	0.0162
MISC I/O CONT.	0.356	0.0253	0.0160
I/O ELEC. POWER	0.121	0.0166	N/A
I/O HYDR. POWER	0.005	0.0371	0.0024
ALARM LAMP (50%)	0.169	N/A	N/A
MEMORY BOARD	0.699	N/A	N/A
MOTHER BOARD	1.72	0.030	0.002
VIDEO DRIVER	1.28	N/A	N/A
TOTAL SYSTEM CURRENT	**+5**	**+12**	**-12**
	4.95	0.302	.008